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Sensory Modulation Disorder in Puerto Rican Preschoolers: Associated Risk Factors

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Sensory Modulation Disorder in Puerto Rican Preschoolers: Associated Risk Factors

A Dissertation submitted in partial fulfillment of the requirements for the degree of
Doctor of Philosophy at Virginia Commonwealth University

by

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ABSTRACT

SENSORY MODULATION DISORDER IN PUERTO RICAN PRESCHOOLERS: ASSOCIATED RISK FACTORS

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A Dissertation submitted in partial fulfillment of the requirements for the degree of
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Sensory Modulation Disorder (SMD) reduces a child's ability to respond to sensory stimuli in the environment in a manner that corresponds to the nature or intensity of the stimulus; this disorder therefore significantly can impact participation in developmentally appropriate play and functional activities. More studies are needed to enhance research in the field of SMD and aid the general community in understanding the disorder and its causes. The purpose of this study was to characterize the prevalence of SMD among Puerto Rican preschoolers and examine the relationship between specific risk factors (socioeconomic status, pre-natal alcohol exposure, low birth weight, preterm delivery, and lead exposure) and SMD in this population.

The sample consisted of 141 caregivers of preschool children; 78 were from Head Start programs and 63 were from private preschools. The Short Sensory Profile was used to determine the presence of SMD. A Demographic and Risk Factors Data Sheet was used to obtain information about the risk factors, except for lead exposure, which was measured using results of blood lead levels tests available in the records of Head Start preschoolers.

Prevalence of SMD among the total sample, calculated through descriptive statistics, was 19.9%, which is higher than previously reported estimates of studies with children on the US mainland. According to an Analysis of Variance test, no differences were found in the prevalence of SMD based on parents' education and/or household income. Diverse multivariate analyses, including structural equation modeling, were used to determine the relevance of risk factors used to explain variance in SMD scores. Due to limitations of the data collected, it was not possible to provide a definite conclusion about the most relevant risk factors identified in this study. In general, when compared to the other risk factors included, findings point to household income and low birth weight as relevant variables to explain scores on the SSP for the total sample. For the Head Start sample, lead exposure and low birth weight, followed by household income, achieved the better relative relevance to explain scores in the SSP (when compared to the other risk factors considered). However, due to the low effect sizes and low percentage of shared variance found among the variables, findings from this study do not support strong associations between risk factors and SMD as suggested in previous literature. More

research is required to further understand SMD and the complex interaction among potential risk factors that might be associated with its prevalence.

CHAPTER I

Introduction

Problem Statement

A healthy child is able to develop the capacity to interact with his biological, physical, and social environment. While there are many disorders with the potential to impact that capacity, Sensory Modulation Disorder (SMD) has not received much attention. SMD places children at risk for poor health status by limiting their capacity to respond adequately to sensory challenges (e.g., tactile, movement, auditory, etc.) in the environment. This reduced ability to behave in correspondence to daily situations where sensory challenges exist, such as hygiene and grooming routines or meal time tasks, secondarily impacts participation in developmentally appropriate play and functional activities (Lane, Miller & Hanft, 2000; Parham & Mailloux, 2001). Therefore, SMD is an important disorder to be aware of in the development of children and more studies are needed to help researchers, practitioners, and the general community understand the disorder and its causes.

Awareness of this need marked the direction of this study in two distinct ways. First, some risk factors associated with poor developmental outcomes, such as pre-natal alcohol exposure, low birth weight (LBW), pre-term delivery (PTD), and lead exposure have been linked in some cases with SMD (Case-Smith, et al., 1998; Franklin, et al.,

2008; Schneider, et al., 2007; Walker, et al., 2009). However, this literature is limited and inconclusive. Studies linking SMD with LBW and PTD are few, and those dealing with prenatal alcohol and lead exposure have used only primate models. Available evidence also suggests that socioeconomic status increases the potential impact of these risk factors, but again no direct impact on the development of SMD has been established (Chambers, et al., 2005; Gee & Payne-Sturges, 2004; Johnson & Schoeni, 2007). This gap in the literature points to a need for research that examines these risk factors and their relevance to the etiology of SMD.

Secondly, while research on SMD has shown significant growth over the past 10 years (Schaaf & Davies, 2010), no study has examined the prevalence of SMD within Hispanic groups. Among children of Hispanic origin, Puerto Rican (PR) children are of particular interest because they represent a growing Hispanic community in the United States. Yet due to their separation from the mainland, they have their own set of health risks and challenges. No study to date has examined the prevalence of SMD among PR children; furthermore, little is understood about the relationship between health disparities and the noted risk factors in this population. Thus, the purpose of this study was to determine the prevalence of SMD in a sample of Puerto Rican children, while exploring potential relationships between SMD and the identified risk factors: socioeconomic status, pre-natal alcohol exposure, LBW, PTD, and lead exposure.

Introduction to Sensory Modulation Disorder

Sensory modulation refers to the ability of an individual to regulate and organize responses to sensations in a graded and adaptive manner, congruent with situational

demands (Parham & Mailloux, 2001). Child health refers to the extent to which children are able or enabled to develop and realize their potential, satisfy their needs, and develop the capacities that allow them to interact successfully with the biological, physical, and social environment (National Research Council and Institute of Medicine, 2004). By enabling the individual to adequately respond to situational demands, sensory modulation becomes part of a repertoire of skills needed to interact successfully within the environment. When an individual responds to sensory inputs from his daily environment in a manner disproportional to those inputs, and this ongoing pattern of response impacts development of functional behavior or participation, he or she is thought to have a Sensory Modulation Disorder (SMD) (Lane, Miller & Hanft, 2000).

An example of a situation that might elicit a disproportional response would be the child who, while standing in a line, gets casually touched (tactile sensory input) by one of the other children in the line. A typical response would be to either ignore or step away from the other child. A disproportional response from a child with SMD may be to physically strike out at the other child, to *fight* or to *self-protect*, to *escape* the situation by running out of line, or to *melt-down* because the touch was so uncomfortable that it led to a state of behavioral overload. SMD can therefore impact the way in which an individual interacts within the physical and social environment and can in turn, have an impact on the child's overall health and well-being. In some children SMD has been shown to specifically impact occupational areas such as play, social participation, and education (Ashburner, Ziviani, & Rodger, 2008; Bundy, Shia, Qi, & Miller, 2007; Cosbey, Johnston, & Dunn; 2010).

While the impact of SMD is fairly well described at the individual (child/person) level, more research is needed to understand the impact of SMD at the community level; prevalence estimates are a first step. Estimates of SMD occurrence in kindergarteners indicate a prevalence of approximately 5 to 14% (Ahn, Miller, Milberger, & McIntosh, 2004). In addition, prevalence estimates of sensory processing disorders based on clinical experience have ranged from 5% to 10% (Ayres, 1989). Estimated rates derived from research studies of sensory processing disorders for children with various disabilities are reported to be as high as 95% (Baranek, David, Poe, Stone, & Watson, 2006; Rogers, Hepburn, Wehner, 2003; Tomcheck & Dunn, 2007; Watling, Deitz, & White, 2001). A more recent study investigated the prevalence of sensory over-responsivity in a sample of elementary school aged children (7 to 11 years) based on the reports from parents about the behavior of their children. From the total sample of parents ($n = 1,491$), 16% reported their children presented behaviors of sensory over-responsivity (especially of tactile and auditory sensitivity) (Ben-Sasson, Carter, & Briggs-Gowan, 2009). These studies suggest that SMD may be an important health factor to consider in working with children in the general population and planning for health-related services in populations of children likely to have SMD.

Estimates of SMD prevalence are similar or even higher than prevalence statistics of other commonly known disorders such as Attention Deficit/ Hyperactivity Disorder (ADHD), which as stated by the American Psychiatric Association (2000) occurs in approximately 3 to 7% of school age children. More recent estimates indicate that as of 2007, approximately 9.5% of children between 4-17 years of age have been diagnosed

with ADHD (CDC, 2010). There is evidence that children with conditions like ADHD, Autistic Disorders, Obsessive Compulsive Disorders, and Mood Disorders might display sensory modulation issues. Emotional behaviors such as anxiety, anger, and emotional lability, as well as attentional difficulties like distractibility, disorganization, impulsivity, and hyperactivity, are commonly observed in children with SMD (McIntosh, Miller, Shyu, & Hagerman, 1999). Nonetheless, research indicates that SMD is a syndrome that can occur either with other disorders, such as ADHD and autism, or as a separate condition (Miller, Reisman, McIntoch, & Simon, 2001; Reynolds & Lane, 2008). Despite these facts, SMD is still not well recognized or understood by the medical and general community. The intent of this study is to contribute to and expand the body of knowledge and general comprehension about SMD by examining its prevalence and relationship with identified risk factors among a population that has not been studied before (Puerto Rican preschoolers).

Previous Research: Risk Variables and Sensory Modulation

No definite cause has been established for SMD. Recent research studies have examined neurophysiologic and neuroendocrine associations with SMD (Mangeot, Miller, McIntosh, McGrath-Clarke, Simon, Hagerman, et al., 2001; McIntosh, Miller, Shyu, & Hagerman, 1999; Reynolds, Lane, & Gennings 2009), while others have looked at associations with situational and environmental variables (Franklin, Deitz, Jirikowic, & Astley, 2008; Pizzano-Smith, 2007; Reynolds, Shepherd, & Lane, 2008; Scheneider, Moore, Gajewski, Laughlin, Larson, Gay, et al., 2007; Walker, Franck, Fitzgerald, Myles, Stocks, & Marlow, 2009). These studies suggest that the prevalence of SMD may be

greater in children from low socioeconomic status and that related factors like exposure to environmental contamination by lead, prenatal exposure to alcohol, low birth weight, and pre-term delivery, may be associated with higher prevalence of SMD. These variables along with socioeconomic status were examined in this study and labeled together as risk factor variables. Additionally, prenatal nicotine exposure was also of interest because of its direct association to low birth weight and pre-term delivery (Kramer, Séguin, Lydon, & Goulet, 2000; Peacock, Cook, Carey, Jarvis, Bryant, & Anderson 1998).

Lending support to the idea that socioeconomic status may be a risk factor for SMD, one study found that children from the inner city, of low socioeconomic status, and of non-white ethnic backgrounds had more problems processing sensory information compared to a normative sample of children in the United States, suggesting a higher prevalence of SMD (Pizzano-Smith, 2007). In another study, a sample of urban African American children from low income households were two and a half to three times more likely to meet the criteria for SMD when compared to previously reported prevalence data taken from a primarily Caucasian and suburban population (Reynolds, Shepherd, & Lane, 2008). While the potential connection between SMD and SES is merely speculative at this point, there is preliminary data to suggest either a direct or indirect connection. Researchers have argued that low income communities encounter greater exposure to environmental toxicants such as air pollution, pesticides and lead and that these factors may be responsible for some types of health disparities (Gee & Payne-Sturges, 2004). Examination of primate models has indicated that SMD may be related to exposure to

environmental hazards such as lead and to prenatal alcohol and stress (Schneider, Moore, Gajewski, Laughlin, Larson, Gay, et. al., 2007). Therefore, low SES may be a risk factor due to intermediary factors associated with the environment.

In addition to pointing at SES and environmental toxicants, specifically lead, as risk factors for SMD, there is evidence that many high risk infants, (i.e., infants who are born prematurely, low birth weight, or those born at risk due to abuse, neglect, or prenatal substance exposure) exhibit fragile self-regulation abilities and difficulty achieving and maintaining a state of normal regulation (i.e., regulation of arousal states from sleepy to awake) (Case-Smith, Butcher, & Reed, 1998; Schaaf & Roley, 2006). These regulatory disorders are often associated with sensory processing impairments (Williamson & Anzalone, 2001). Nonetheless, still more evidence is needed to understand the link between identified risk factors and SMD. This aspect has not been broadly studied in the human population and has not been studied at all in the Hispanic population, which is part of what this study intended.

Purpose Statement

The purpose of this study was to characterize the prevalence of SMD among PR preschoolers and examine the relationship between identified risk factors and SMD in this population. Participants in this study were PR preschoolers from Head Start centers and private preschools. Specific aims of this study were as follows:

1. To establish the presence and examine the prevalence of SMD in a sample of PR preschoolers from different SES backgrounds.

- a. It was hypothesized that prevalence rates determined in this study would be higher than those reported in previous research with children from the US mainland.
 - b. It was hypothesized that SMD (as indicated by total scores of the SSP) would be higher among preschoolers whose caregivers have lower educational degrees and lower household incomes.
2. To determine if relationships between sensory modulation and the identified risk factors could be explained by an exploratory path analysis model. Figure five in Chapter Two presents a diagram that illustrates the hypotheses related to this aim.
 - a. It was hypothesized that moderate relationships between SES and prenatal alcohol exposure, SES and prenatal nicotine exposure, and SES and lead exposure would be observed.
 - b. It was hypothesized that SES and prenatal alcohol exposure would be the variables with the higher directional linear associations with SMD (as long as lead exposure is not considered as part of the analysis).
3. To explore changes in the relationships between sensory modulation and the identified risk factors when the variable lead exposure is included as an additional risk factor in a second exploratory path analysis model.
 - a. It was hypothesized that, once lead exposure was included as part of the analysis, SES and lead exposure would be the variables with the highest directional linear associations with SMD.

Significance of the Study

Despite the suggested association between SES and SMD evidenced in prior prevalence studies (Pizzano-Smith, 2007; Reynolds, Shepherd, & Lane, 2008), such a relationship has rarely been directly studied. Literature indicates that children with SMD are usually from a minority ethnicity, live with a single parent and/or a non-employed parent, and are from a lower economic status (Ben-Sasson, Carter, & Briggs-Gowan, 2009). However, studies so far examining the prevalence of SMD among minorities or low SES groups have not included a comparison group. Issues such as this have led to a lack of understanding of SMD in terms of health disparities.

This study is the first effort in PR to get an estimate of the prevalence of SMD among children. It is also the first SMD prevalence study made within a Hispanic community (outside of the United States). In an effort to contribute to a better understanding about SMD and health disparities, this study considered a group of risk factors, not only in terms of their relationship with SMD, but also in terms of the vulnerability that disadvantaged groups have to those factors and to SMD. For this purpose, an exploratory path analysis model was elaborated based on a broad literature review. The use of such a model was intended to allow the examination of more complex relationships between the identified risk factors and SMD.

Additionally, it should be noted that the relationship between lead exposure and SMD has been studied only through the use of primate models (Moore, et al., 2008; Scheneider, et al., 2007). This current project included lead exposure as one of the risk

factors variables in the path analysis model, providing new preliminary evidence about the association of lead exposure to SMD in a sample of human subjects.

Understanding of SMD in conjunction with SES, prenatal alcohol exposure, low birth weight, pre-term delivery, lead exposure, and prenatal nicotine exposure is essential for the health community in Puerto Rico and outside of the island. Diverse developmental impacts of these risk factors have been documented in the literature (Burden, Jacobson, Sokol, & Jacobson, 2005; Gee & Payne-Sturges, 2004; Stoelhorst, Martens, Rijken, Zwieten, Zwinderman, & Veen, 2003). Younger children represent a group particularly vulnerable to these variables. Research has shown that young children (six years of age or younger) are more susceptible to contamination by lead exposure because they can absorb as much as 50% more lead than adults (who absorb from five to ten percent of ingested lead) (Sánchez-Nazario, Mansilla-Rivera, Derieux-Cortés, Pérez, & Rodríguez-Sierra, 2003).

Further, there is a lack of awareness in PR about SMD and the occupational performance deficits associated to it. This preliminary prevalence estimate may help to bring necessary attention to this disorder. Additionally, obtaining data about the risk factors related to SMD from a sample of preschool children provides evidence to justify the importance of emphasizing prevention and early identification, as well as guidance in terms of the community groups that deserve primary attention. Such efforts are particularly important because of their significance in terms of how primary and secondary prevention can be used to ameliorate the impact of SMD, as well as associated health conditions.

CHAPTER II

Literature Review

Theories guiding this study, Sensory Integration Theory and the Vulnerability Model, are discussed in this section as foundations to support and better understand the purposes of this project. Constructs pertaining to each of these theories, connections between these theories, and links to the variables included in this study are detailed. As one of the primary focuses of this study, emphasis is placed on sensory modulation as an aspect of Sensory Integration Theory. Special attention is also paid to developmental risk factors associated with sensory modulation and the different areas of child development they can affect. Research studies that have linked these risk factors to SMD are presented. Finally, a brief summary is offered emphasizing the significance and rationale for the study based on the literature review.

Sensory Integration Theory

Sensory Integration Theory describes the hypothesized relationship between adequate neural organization and processing of sensations and an individual's ability to learn and deal with sensory challenges that are inherent in daily life. Bundy and Murray (2002) specifically state that Sensory Integration is a theory of brain-behavior relationships. A more detailed explanation indicates that Sensory Integration Theory “refers to constructs that discuss how the brain processes sensations and the resulting

motor, behavior, emotion, and attentional responses” (Miller, Anzalone, Lane, Cermak, & Osten, 2007, p.135).

Sensory Integration Theory is based on three major postulates. The first one involves learning, which “is dependent on the ability to take in and process sensation from movement and the environment and use it to plan and organize behavior” (Bundy & Murray, 2002, p.5). The second postulate states that “individuals who have a decreased ability to process sensations may also have difficulty producing appropriate actions, which in turn, may interfere with learning and behavior” (Bundy & Murray, 2002, p.5). The third component is that “enhanced sensation, as part of meaningful activity that yields an adaptive interaction, improves the ability to process sensation, thereby enhancing learning and behavior” (Bundy & Murray, 2002, p.5).

The five assumptions underlying Sensory Integration Theory include concepts related to: (1) the plasticity of the Central Nervous System (CNS); (2) the sequential development of sensory integration, with each stage allowing for more complex behaviors; (3) the brain functioning as an integrated whole; (4) the promotion of sensory integration through adaptive interactions with the environment and vice versa; and (5) the importance of inner drive and motivation to develop sensory integration through participation in sensorimotor activities (Bundy & Murray, 2002).

It is important to note that, although sometimes the term sensory integration is used interchangeably with the term sensory processing, they do not necessarily refer to the same thing. Sensory processing involves the reception, modulation, integration, and organization of sensory stimuli, including the behavioral responses to sensory input

(Miller & Lane, 2000). It refers to the way in which the CNS, as well as the peripheral nervous system, manages incoming sensory information. Sensory processing is a broader term and sensory integration is only one component of sensory processing. It is important to note that both sensory processing and sensory integration are *normal* neurological processes. When there is a breakdown in the processing or integration of sensory information which impacts functional performance in the CNS, then that individual may be considered to have a sensory processing disorder (SPD).

Proposed Nosology for Sensory Processing Disorder

Sensory Processing Disorder (SPD) has been acknowledged outside the field of occupational therapy in diagnostic classification references like the Diagnostic Classification of Mental Health and Developmental Disorders of Infancy and Early Childhood, Revised (DC: 0-3R, Zero to Three, 2005), and the Diagnostic Manual for Infancy and Early Childhood of the Interdisciplinary Council of Developmental and Learning Disorders (ICDL, 2005). Figure 1 presents a nosology for SPD presented by Miller, Anzalone, Lane, Cermak, and Osten (2007).

The proposed nosology includes three classifications of SPD: Sensory Modulation Disorder (SMD), Sensory-Based Motor Disorder (SBMD), and Sensory Discrimination Disorder (SDD). Sensory discrimination refers to the individual's ability to interpret and differentiate between the spatial and temporal qualities of sensory information (Schaaf, Schoen, Smith Roley, Lane, Koomar, & May-Benson, 2010). Discriminative functions contribute to skill development, learning, social interactions, and play (which involves fine motor responses such as in object manipulation). Each sensory system has its

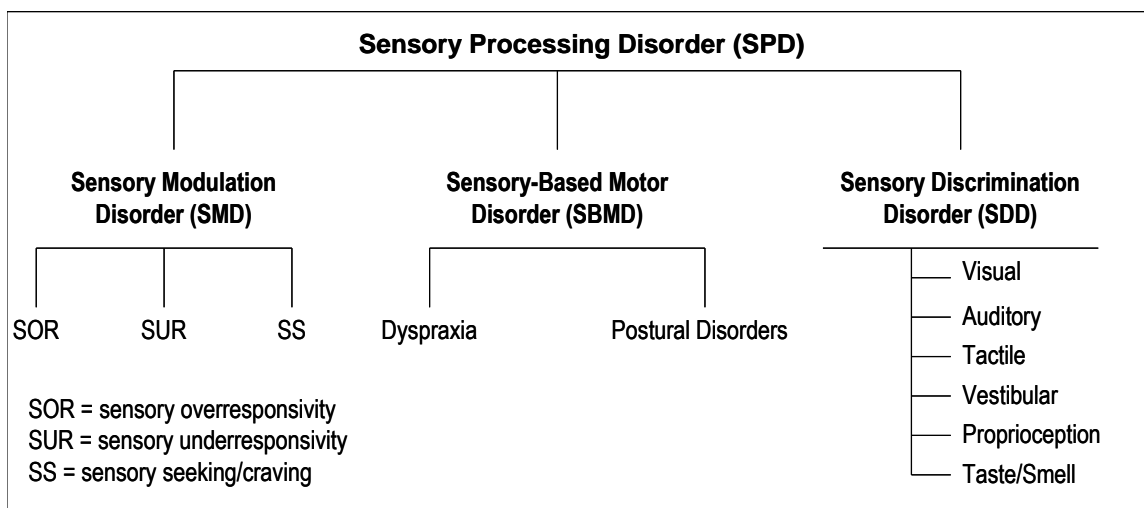


Figure 1. Proposed Nosology for Sensory Processing Disorders (Miller, Anzalone, Lane, Cermak, and Osten, 2007)

respective discriminative function (Schaaf, et al., 2010). For example, tactile discrimination provides information about spatial and temporal qualities of the environment by perceiving the qualities of information from skin receptors. Similarly, vestibular discrimination allows the individual to know where the head is in relation to the rest of the body and in relation to the environment. It provides information about the effect of gravity, and the speed and direction of body movements. Normal sensory discrimination provides accurate interpretation of sensory stimulation, which is the basis for feed-forward mechanisms for planning movement and postural responses. Thus, when a SDD is present, children might present awkward motor abilities, and learning or language disabilities.

The second classification of disorders included in the nosology is SBMD and its respective subtypes: Dyspraxia and Postural disorders. Postural disorder is identified by “difficulty stabilizing the body during movement or at rest to meet the demands of the

environment or of a given motor task” (Miller, et al., 2007, p. 138). Difficulty in body stabilization might be seen in children with hypotonic or hypertonic tone, inappropriate muscle tension, poor righting and equilibrium reactions, or inadequate muscle contraction against resistance. Dyspraxia, as defined by Miller and colleagues (2007, p.138), is “an impaired ability to conceive of, plan, sequence, or execute novel actions.” Children with Dyspraxia look poorly coordinated in gross, fine, or oral-motor skills. They might be unable either to generate new ideas about what to do, have difficulty performing tasks that require adaptation of timing in movement, and/or difficulty in manipulative activities (even those included in their daily routines like manipulation of cutlery or fasteners).

SBMD and SDD might occur in the presence of each other, or in the presence of Sensory Modulation Disorders (SMD). SMD is the focus of this research study and, thus, is explained in more detail below.

Sensory Modulation Disorder (SMD).

Sensory modulation refers to the regulation of neural messages about sensory stimuli. SMD occurs when an individual has difficulty responding to sensory input with behavior that is graded relative to the degree, nature, or intensity of the sensory information (Miller, et al., 2007). An individual with SMD is often not able to respond adaptively to environmental demands. As defined by Ayres (2000), an *adaptive response* is a purposeful, goal directed response to a sensory experience. Lack of ability to produce adaptive responses can turn events of daily life into great challenges for individuals with SMD. Three subtypes of SMD are included in the nosology of Miller and colleagues:

1. Sensory over-responsivity (SOR) - As opposed to individuals with typical sensory responsiveness, individuals with SOR respond to sensation faster, with greater intensity, or for a longer duration (Miller, et al., 2007). Their atypical responses are automatic, unconscious reactions to sensation and might include a range from active, negative, impulsive, or aggressive responses to more passive withdrawal or avoidance of sensations. Sympathetic nervous system activation is characteristic of SOR (Miller, et al., 2007). Exaggerated emotional responses (i.e., fight, flight, fright, or freeze responses, as described by Ayres, 1972) might be observed.
2. Sensory Under-responsivity (SUR) – Individuals with SUR appear not to detect sensory information. They might be described as being apathetic, lethargic, or showing lack of inner drive to initiate socialization and exploration. However, more than being affected by a lack of motivation, individuals with SUR are affected by a failure to notice the possibilities for action. That is why they need high intensity salient input to become involved in tasks or interactions (Miller, et al., 2007).
3. Sensory Seeking (SS) – SS is described as an intense, insatiable desire for sensory input (Miller, et al., 2007). Available input seems to be less than enough for the individual to feel satiated. Thus, the individual engages in actions designed to create a more intense sensation (e.g., constant movement, touching, watching moving objects, or seeking loud sounds). Actions of people

with SS are often interpreted as demanding or attention-seeking behavior (Miller, et al., 2007).

The nosology of Miller and colleagues is useful to examine the behavioral aspects of sensory modulation, referring to the individual's ability to regulate and organize responses to sensations in a graded and adaptive manner, congruent with situational demands (Ayres, 1972). However, sensory modulation also has a neurophysiological component. Physiologically, modulation refers to cellular mechanisms of habituation and sensitization, which alter the structures and/or function of nerve cells, affecting synaptic transmission (Kandel, 2000). Therefore, it is hypothesized that dysfunctional behavior patterns in SMD are related to underlying neurophysiologic processes.

Neurophysiologic Processes and Sensory Modulation

Lane (2002) explains that within the central nervous system (CNS), modulation is reflected by neuronal activity, which can be enhanced or dampened in response to various sources of stimuli. The vast majority of cells within the CNS communicate through synaptic transmission, and neurons influence the excitability of adjacent cells through this process (Shepherd & Koch, 2003). Chemicals contained in the presynaptic terminal, called neurotransmitters, are released into the synaptic cleft to transmit information between neurons. The properties of the receptors that recognize and bind neurotransmitters determine whether excitation or inhibition of a neuronal impulse will occur at the postsynaptic site (Kandel, 2000).

An excitatory input can lead to the generation of an action potential. Action potentials are electrical signals that can be repeatedly regenerated to transmit information

among neurons that will ultimately be received and analyzed in the brain (Lundy-Ekman, 2007; Kandel, 2000). To produce an action potential, the neuron's membrane must be depolarized to its critical level. That critical level of depolarization is called the threshold (Bear, Connors, & Paradiso, 2007). On the other hand, an inhibitory input can inhibit the generation of the action potential. In other words, inhibitory inputs reduce the chances of membrane depolarization and action potential generation.

Lane (2002) indicates that there is potential for competing inputs, some excitatory, others inhibitory, some strong, and others weak. It is the sum of inputs (instead of a single input) in conjunction with other factors (e.g., frequency of input, location of the synapse relative to the cell body) that determines whether the signal is or is not propagated. As explained by Lane (2002, p.104), "increasing excitatory inputs result in the postsynaptic cell firing and sending the information forward," while "increased inhibitory inputs will block further transmission of the impulse."

As a result of the type and amount of stimuli, changes in neuronal sensitivity occur. Repeated non-threatening stimuli results in a decreased response due to a decrease in the release of excitatory neurotransmitters, and thus, in the action potential generated. That decrease in synaptic firing, called habituation (Lundy-Ekman, 2007), is associated with a decrease in behavioral response (Reeves, 2001). Behaviorally, habituation might help an individual ignore non-relevant events or distractions in the surroundings and promote focus on the important aspects of situations. Neurologically, by reducing unnecessary synaptic action, habituation can reduce distractibility and adequately adjust the person's usual response to stimuli.

Another neuronal mechanism of interest is sensitization, which entails excessive responsiveness of central neurons developed in response to ongoing salient input. Sensitization occurs when there is an increased availability of excitatory transmitters and an increased number of excitatory receptors (Lundy-Ekman, 2007). The purpose of sensitization is to assist in potentially dangerous situations by alerting the organism. Behaviorally, sensitization might represent the internal events in persons who exhibit defensive reactions to one or more types of sensory stimuli. This increased response can disrupt the ability to override unimportant stimuli. It has been hypothesized that SMD occurs when there is an imbalance or a dysregulation in habituation and sensitization mechanisms in the brain.

CNS Structures and Sensory Modulation

While current understanding of the mechanisms that underlie sensory modulation deficits are primarily hypothetical, specific areas of the CNS have been identified as being involved in aspects of sensory modulation. It has been proposed that modulation has its roots in regions of the limbic system and the hypothalamus. The limbic system includes cortical areas (cingulate gyrus, septum, and parahippocampal gyrus), as well as the gray matter areas of the hippocampus and the amygdala. The hippocampus and the amygdala are the components of greatest interest for purposes of this discussion.

The amygdala is deeply involved in the generation of emotions (Kumai & Shibukawa, 2009). It receives input from the reticular formation and shares reciprocal connections with the cerebral cortex. Input from the reticular formation and its neurotransmitters have the potential to activate the amygdala. In addition, conscious

awareness of emotions occurs when information from the amygdala and from the autonomic system reaches the cortex (Lundy-Ekman, 2007). This is suggested as a mechanism that can moderate the reactions of the amygdala and inhibit over-activation of emotional responses (Reeves, 2001). For example, connections between the amygdala and the temporal lobe can be important in linking memories of past events with current inputs and thus, affect subsequent behavior. Lane (2002) suggests that some of the avoidance behaviors associated with SMD may be related to the attachment of a negative emotional response to that sensory input within the amygdala.

The other component of interest in- the limbic system, the hippocampus, has functions related to memory, perception of space, and inhibition. While the amygdala is deeply related to the generation of emotions, the hippocampus is related to the generation and storage of long term memories (Kumai & Shibukawa, 2009). Sensory perception is the first step of the memory process. To construct a memory of a sensory experience, an appropriate emotion should be attached to the sensation. For example, the sensory memories of eating favorite foods or of ingesting food that caused illness are stored in the hippocampus (Gutman & Schindler, 2007). People tend to repeat pleasurable experiences, and avoid those that cause harm, thus enhancing human survival. As both negative and positive emotions become linked (via stored memories) to sensory experiences, the connections between the hippocampus and stress centers of the brain may become essential for the modulation of new sensory inputs.

Another component of the limbic system, the septum, is believed to be of particular importance for sensory modulation. Cells in the septum produce acetylcholine,

a neurotransmitter that has a facilitatory effect and contributes significantly to attention. Since it enables the individual to attend to any stimulus in the environment (even those of low value), it is thought that in a normal state, the septum contributes to the ability to interact successfully with the environment and, thus, plays a role in sensory modulation (Lane, 2002). More specifically, activity of the septum is thought to exert an inhibitory influence on the autonomic nervous system (ANS) which has been directly linked to SMD-related behaviors such as arousal regulation and physiological responsiveness to sensation.

The ANS consists of the sympathetic nervous system and the parasympathetic nervous system. The parasympathetic portion facilitates grading of arousal and emotional control. It is essential for self-regulation and coordinated actions of body organs and systems. The sympathetic system activates the fight or flight reactions under conditions of perceived threat. Activation of this system heightens arousal and prepares the body for rapid responses (Bear, Connors, & Paradiso, 2007; Lundy-Ekman, 2007). Proper functioning of the ANS is thought to underlie the ability to maintain homeostatic physiological arousal, enabling an individual to react and recover from stressors in the environment. Specifically, the ANS regulates an individual's ability to adapt to environmental changes through modulation of sensory, motor, visceral, and neuroendocrine functions (Iversen, Iversen, & Saper, 2000; Schaaf, Miller, Seawell, & O'Keefe, 2003). It has been stated that children who demonstrate severe over or under-responsiveness to sensation or inability (or both) to restore homeostasis or self-regulation

after a stressful event, might have a disturbance in ANS functions that impacts their participation in activities (McIntosh, Miller, Shyu, & Dunn, 1999).

Structures outside of the limbic system related to the modulation of sensory inputs are the reticular system and the hypothalamus. The hypothalamus integrates somatic, visceral, and behavioral information from other sources, thus coordinating autonomic and endocrine outflow with behavioral state (Iversen, Iversen, & Saper, 2000). Additionally, the reticular system, in particular the reticular formation of the brainstem, is also significantly related to modulation.

The reticular formation is a complex neural network that can be divided into three zones. The lateral zone integrates sensory and cortical input and moderates generalized levels of arousal. The medial zone regulates vital functions, somatic motor activity and attention. The midline zone adjusts the transmission of pain information, somatic motor activity, and consciousness levels (Lundy-Ekman, 2007). The reticular formation plays a role in filtering out irrelevant stimuli, making it possible for salient sensory information to reach higher cortical areas. For example, sensations of pain and light touch warn of danger, facilitating alerting and arousal reactions to enhance survival. Stimulation of the reticular formation with this type of information will increase brain activity to support vigilance and attention at higher cortical levels (Reeves, 2001).

The preceding paragraphs highlight the complexity of the brain and the intricate human behaviors it coordinates and produces. Sensory modulation, in particular, is based on normal functioning of multiple structural areas in the brain and complex cellular processes. Alterations to those structures or processes could in turn result in an inability

to accurately process sensory information and subsequently appear as behaviors we have come to classify as SMD.

Sensory Integration and SMD: Applications to this Study

The discussion presented provides theoretical support for the association of SMD with physiological and behavioral deficits. Miller and Lane (2000) summarized the hypothesized physiological and observed behavioral components of sensory modulation by suggesting that modulating sensation is a multifaceted central process by which the neural messages that convey information about traits of sensory stimuli (e.g., intensity, frequency, duration, and novelty) are adjusted. Instead of being a single process, it is thought that changes in reactivity involve several interacting processes that alter the neurophysiological response to stimuli (Miller & Lane, 2000).

As defined by Ayres (1979, p.11), pioneer of Sensory Integration Theory, sensory integration is “*the neurological process* that organizes sensation from one’s own body and from the environment and makes it possible to use the body effectively within the environment.” Thus, sensory integration occurs at the central nervous system level, where stimuli received from the environment are processed. After processing, the individual produces a behavioral and therefore, observable response. Figure 2 provides an image of this process.

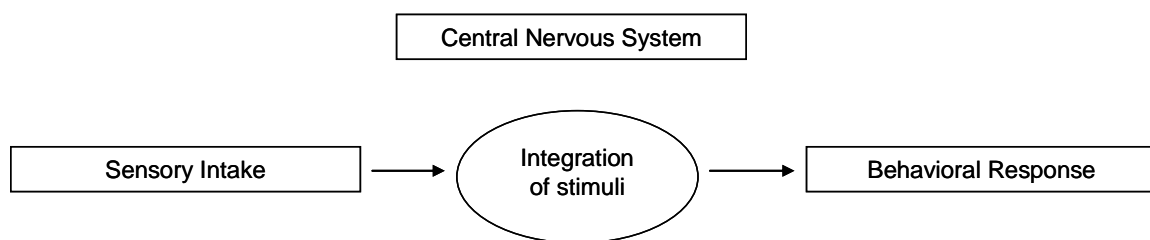


Figure 2. Linear Representation of Sensory Processing

An Overview of Risk Factors in Relation to CNS Development

Research and theory discussed thus far suggests that SMD is a brain-based disorder that manifests in unique behavioral patterns. As other neurological conditions, SMD may be influenced by risk factors occurring prior to or after birth. Among those are the risk factors that will be examined in this study: Socioeconomic status (SES), pre-natal alcohol exposure, low birth weight (LBW), preterm delivery (PTD), lead exposure, and pre-natal nicotine exposure (which is associated with low birth weight and preterm delivery). Many of these risk factors affect the child's neurological development and, thus, the development of CNS structures that, as discussed, are related to sensory modulation.

Evidence indicates that prenatal alcohol exposure alters the functions of neurotransmitters involved in the organization of the CNS during animal fetal development. Through a meta analysis, Costa, Savage, and Valenzuela (2000), found evidence supporting that exposure to alcohol can reduce the number and functions of receptors that are critical for stabilizing synapses formed during sensory and behavioral experiences. Similarly, another meta analysis supports that pre-natal alcohol exposure can cause increased activity in some neurotransmitters (e.g., glutamate), which can induce neuronal death (Goodlett & Horn, 2001). A review of structural imaging studies pointed to alterations in brain shape, changes in cortical thickness, reduced size, and altered shape of the corpus callosum, as well as alterations in the hippocampus (Norman, Crocker, Mattson, & Riley, 2009). Another teratogen that can impact fetal CNS development is nicotine. There is evidence that pre-natal nicotine exposure impacts neurotransmitter

receptors in the fetal brain, leading to reduced cell proliferation and, consequently, altered synaptic activity (Dwyer, McQuown, & Leslie, 2009; Slotkin, 1998).

Synaptic activity can also be affected by lead exposure. Even micromolar concentrations of lead can cause spontaneous release of neurotransmitters (Abou-Donia, 1992). In addition, lead can block the release of neurotransmitters when the action potential is taking place. Lead is also associated with damage to myelin. Myelin is a sheath of proteins and fats that provide support for conduction of the neuron's electrical signals, and helps buffer neurons from the surrounding ionic environment. Demyelination of these membranes results in peripheral neuropathy and decrease in nerve conduction velocity (Abou-Donia, 1992). Studies with rhesus monkeys also indicate that lead exposure throughout gestation and through breast milk might result in lifelong alterations in brain architecture (Lasky, Luck, Parikh, & Laughlin, 2005).

Finally, LBW and preterm delivery (PTD) can also impact structures of the central nervous system. According to Davis (2004), both are associated with risks in brain development, which are more marked the earlier the gestational age. Research supports that very preterm infants (i.e., those born with 33 gestation weeks or less) are at increased risk of brain injury (Cooke & Abernethy, 1999). Investigations of subtle deficits in the brain morphology of preterm children have reported decreased total cerebral tissue volume in the corpus callosum, hippocampus, amygdale, sensory motor cortex, cerebellum and basal ganglia (Abernethy, Palaniappan, & Cooke, 2002; Isaacs, et al., 2000; Peterson, et al., 2000). Additional analysis controlling for variables such as gender and height indicate that adolescents born very preterm present with a 6.0%

decrease in whole brain volume, 15.6% decrease in right and 12.1% decrease in left hippocampal volumes, as well as a 42% increase in the size of the lateral ventricles (Nosarti, Al-Asady, Frangou, Stewart, Rifkin, & Murray, 2002). Kesler, Ment, Vohr, Pajot, Scheneider, Katz, et al. (2004) state that preterm birth appears to be associated with disorganized cortical development, possibly involving disrupted synaptic pruning and neural migration.

Through their influence on neurological structures and functions, risk factors can influence individual behavioral responses. Sensory Integration Theory provides the foundation to look at the link between risk factors, impact on nervous system, and impact on behaviors associated with Sensory Modulation Disorder. In addition, the General Model of Vulnerability provides a framework to further explore these variables as risk factors from a community and individual perspective. Also, it provides the base to examine SES, another variable of interest in this study, as a factor related to the person's overall health and ability to access resources.

General Model of Vulnerability

Vulnerability has been defined as a multidimensional construct reflecting a convergence of many risk factors at both the individual and community levels, which influence health and healthcare experiences (Shi, Stevens, Lebrun, Faed, & Tsai, 2008). Based on Aday's individual and community interaction model, Shi and Stevens' model (2005) recognizes the convergence of individual, social, community, and access to care as risks that lead to vulnerability.

Vulnerability implies susceptibility to poor health, which can be manifest physically, mentally, developmentally (as with developmental delays in children), or socially (see “Health outcomes” in Figure 3). It can be proposed that children with SMD might experience limitations related to the developmental and social dimensions of health due to deficits in their ability to adequately register, interpret and respond to the information from their environment. Poor health in one dimension might be accompanied by poor health in other dimensions as well. The Vulnerability Model suggests that health needs are greater for those with multiple health problems than for those with single health issues (Shi & Stevens, 2005).

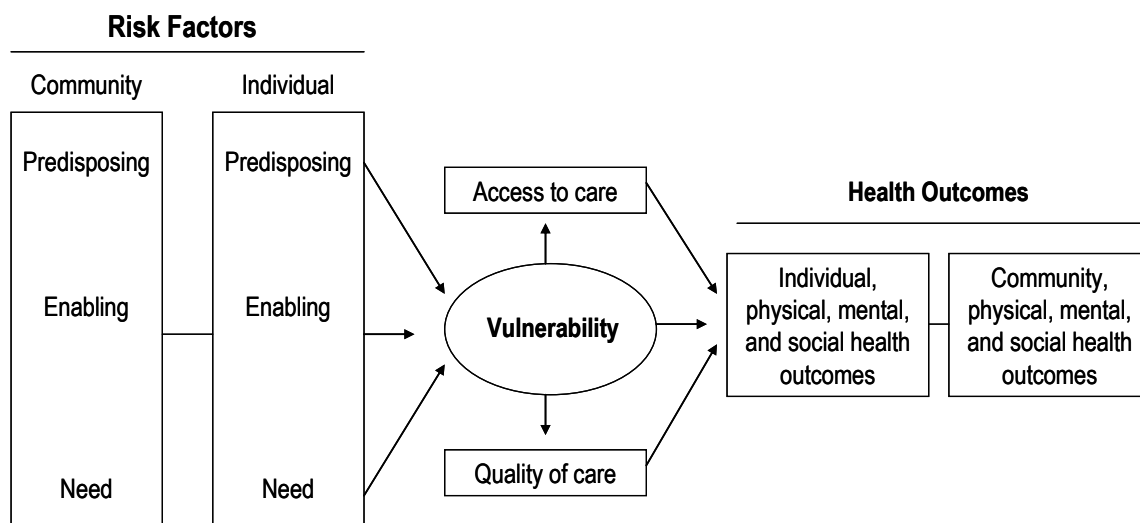


Figure 3. Shi and Steven's (2005) General Model of Vulnerability

As shown in Figure 3, a convergence of predisposing, enabling, and need characteristics at both the individual and ecological/community levels determines individual's and group's vulnerability for poor health.

Shi and Steven (2005) indicate that the General Model of Vulnerability emphasizes the importance of vulnerability determinants at community or ecological

levels. In their model, vulnerability “does not represent any personal deficiency of the populations defined as vulnerable, but rather that they experience the interaction of many risks factors over which individuals have little or no control” (Shi & Steven, 2005, p. 17). When attributes of vulnerability are beyond the individual’s control, their abatement requires government and societal efforts. Risk factors (under and beyond the individual’s control) impact the level of vulnerability of a population. Vulnerable populations usually lack access to care or receive care of non-optimum quality. This has an effect on health outcomes for the individual, but also for the community. Thus, predisposing, enabling, and need attributes represent risk factors for poor access, poor quality of care, and poor health outcomes.

Following Aday’s definitions, under the General Model of Vulnerability (2005), predisposing characteristics at the *individual level* are those that describe the propensity of individuals to use services, which include basic demographic characteristics (e.g., age, gender, family size, race/ethnicity, education, employment, occupation, health beliefs, and health behaviors). Enabling characteristics refer to the means that individuals have available for the use of services (e.g., income, insurance coverage) and to the attributes of the community in which the individual lives (e.g., availability of health care services). Need factors are specific illness or health needs that are the driving forces for receipt of health care (Shi & Steven, 2005).

At the *ecological or community level*, predisposing attributes include neighborhood demographic composition (e.g., racial/ethnic integration or segregation), physical environment (e.g., pollution, urban violence), political, legal, and economic

systems, and cultural and social norms or beliefs. Enabling risk factors include socioeconomic position in relation to others, workplace environments, social resources, and health care delivery system factors (e.g., social class, workplace stress, social capital, accessibility of preventive and public health). Community need attributes include community health risk factors such as pollution levels, health promoting community behaviors, and trends in health status and health disparities (Shi & Steven, 2005).

In general terms, under the Vulnerability Model, *health needs* directly imply vulnerability, *predisposing characteristics* indicate the propensity of vulnerability, and *enabling characteristics* refer to the resources available to overcome the consequences of vulnerability (Shi & Stevens, 2005).

Using the vocabulary of the model, this study looked at a variety of individual and community risk factors that influence the prevalence of SMD, which was the health outcome measured. Figure 4 illustrates the way in which Sensory Integration and the Vulnerability Model were integrated conceptually for purposes of this study.

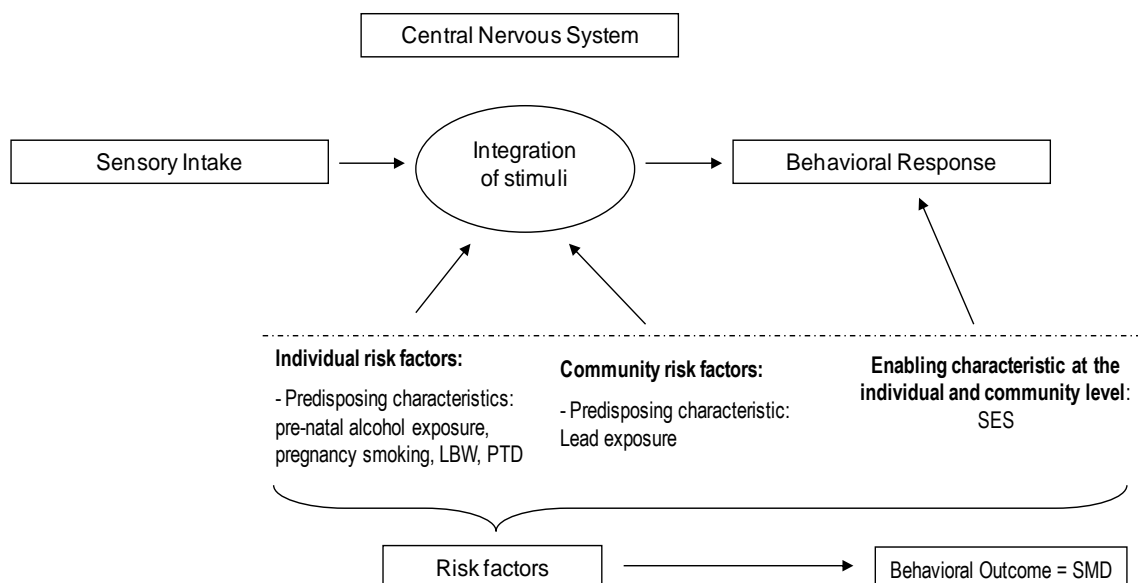


Figure 4. Combination of the Sensory Integration Theory and the Vulnerability Model

Predisposing characteristics that were considered at the individual level as risk factors were pre-natal alcohol exposure, pre-natal nicotine exposure, low birth weight, and preterm delivery. Lead exposure was examined as a risk predisposing characteristic at the community level. Since, as discussed, these variables can impact the functions and structures of the central nervous system (CNS), it is inferred that these predisposing risk factors (located below the horizontal dashed line of Figure 4) impact the neurophysiological aspects of sensory modulation. The model presented in Figure 4 recognizes that impact, although it should be clarified that measures used in this study will be related only with the risk factors (e.g., birth weight, gestational age when born, blood lead levels) and not their direct impact on the CNS. SES is labeled as an enabling characteristic at the individual and the community level. Since one of the purposes of the study was to examine the prevalence of SMD in terms of SES, there was a special interest in looking not only at the SES of each of the participants (individual level), but also in looking at possible differences between groups classified according to their SES (community level). As will be discussed in the following sections, SES is more often associated with behavioral features versus having a direct impact on the nervous system. Thus, it has been located below the square of “behavioral outcome” in Figure 4.

Under the model by Shi and Stevens (2005), vulnerability is determined by the interaction of individual and community level risks. The model emphasizes the convergence of risks that have additive or multiplicative impacts on health (Shi, Stevens, Lebrun, Faed, & Tsai, 2008). In correspondence to the model, this study examined the

association between the convergence of a group of risk factors and the prevalence of SMD.

Risk Factors Considered in this Study

Socioeconomic Status: An Enabling Characteristic

Socioeconomic status (SES) is identified as an enabling characteristic in Shi and Steven's (2005) model since it is related to the person's ability to access resources. SES denotes the relative position of individuals, families, or groups into stratified social systems (Grusky, 1993). In their analysis about socioeconomic resources and racial and ethnic gaps in students' test scores, Duncan and Magnuson (2005) indicate that the key advantage bestowed by higher income is a stimulating learning environment. They state that the number of books and newspapers in the home and the access of children to learning experiences routinely explain about a third of the effects of poverty.

Among the dimensions typically associated with SES are occupational status, educational achievement, income, poverty, and wealth (Agency for Healthcare Research and Quality, 2008). These dimensions have been related to developmental and school outcomes of children. For example, family processes that might indirectly link parent education and other family background indicators, such as income, with child academic achievement have been examined (Davis-Kean, 2005). Findings suggested that parents' education level influenced child achievement indirectly through its impact on the parents' achievement beliefs and stimulating home behaviors. However, in the referenced study, only average income for families in the study was represented (\$48,178), which did not allow for a direct comparison of low and high income families.

Outcomes related to SES have also been studied in different ethnic and community disadvantaged groups. One study examined children's social skills and problem behavior as outcomes for a group of mothers and their children who were primarily African American and from low income families. Results suggested that low income, as a single factor, did not predict children's outcomes. However, a number of risk factors (e.g., parent unemployment, single parents, lower parent education), which are more common among the low-income population, did have a cumulative effect for risk (Hawthorne, 2004). Parents of this study who reported more supportive parenting practices indicated lower levels of stress related to parenting their child. Also, teachers indicated that the children of these parents had better social skills and fewer problem behaviors. It is specified that, in this study, parental stress measures were a reflection of parenting quality. Findings also suggested that stress might be indirectly a result of financial strain since limited access to resources directly impact parents' stress, which indirectly affects parenting quality and parent-child interaction (thus, the cumulative effect for risk) (Hawthorne, 2004). Other variables such as lower scores on intelligence tests, cognitive function, lower levels of school achievement, and increased levels of socio-economic problems have also been correlated to poverty level, low SES, and residence in economically disadvantaged neighborhoods (McLoyd, 1998).

Research from different disciplines has linked SES to risk factors of interest in this study. Evidence suggests that disadvantaged communities encounter greater exposure to top environmental toxins, which subsequently impacts health (Gee & Payne-Sturges, 2004). In their "Framework integrating psychosocial and environmental concepts," Gee

and Payne-Sturges (2004) state that environmentally relevant disparities are evident in a variety of health outcomes, such as asthma, cancer, and chemical poisoning.

Incidence of smoking during pregnancy, LBW, preterm delivery and alcohol use during pregnancy also seem to be higher among mothers with lower educational levels or incomes. The prevalence of smoking during pregnancy has been inversely related to maternal education. In the United States, only 2% of college-educated women reported smoking during pregnancy in 2000, while 25% of pregnant women who attended but did not complete college smoked (Martin, Hamilton, Ventura, Menacker, & Park, 2002). Findings of studies with low-income pregnant Latinas indicate percentages of maternal alcohol consumption as high as 43% in the three months prior to recognition of their pregnancy (Chambers, Hughes, Meltzer, Wahlgren, Kassem, Larson, et al., 2005); and 24% post conception (O'Connor & Whaley, 2003). Furthermore, low or no maternal education is a major positive risk factor for having a low birth weight child (Letano & Majelantle, 2001). In addition, mothers registered for Medicaid (a health services program geared towards the low income population) are significantly more likely to have a preterm and/or low birth weight infant than those in other public insurance programs that, in addition to serving particular low income groups (e.g., undocumented women), also serve some higher income women not eligible for Medicaid (Dang, Dessel, Hanke, & Hilliard, 2011).

Evidence is also available about the relationship between SES and outcomes affecting children's health and developmental outcomes. Different explanations as to why low SES is related to such poor outcomes have been proposed (Shi & Stevens, 2005). For

example, low income groups experience greater difficulty paying for basic health and social needs. Also, despite the existence of health insurance programs for poor individuals, low SES groups have less financial access to health care services. This explains why SES is considered an enabling characteristic under the Vulnerability Model (Shi & Steven, 2005). In general terms, SES influences not only the ability to receive treatment when health problems occur, but also the ability to promote health and protect individuals from undesirable outcomes.

Socioeconomic Status and SMD

SMD has rarely been studied in regard to SES. However, there is evidence that socio-demographic characteristics such as being of a minority ethnicity, living with a single parent and/or a non-employed parent, and being of low socio-economic status are frequently noted among children presenting high SOR scores (Ben-Sasson, Carter, & Briggs-Gowan, 2009). Some studies have examined sensory processing difficulties among children of low socioeconomic status. Pizzano-Smith (2007) used the Sensory Profile, a 125 items caregiver questionnaire, for the purpose of examining its validity with an inner city population referred to a mental health clinic. The study used a convenience sample from an archival data set from 2001-2006 which included 60 children ranging from 4 to 10 years of age referred for mental health treatment at a Youth Consultation Services Facility in New Jersey. Subjects were predominantly from the inner city, of low SES and of non-white racial groups. No specifications were provided regarding which variables were considered to define SES, although information was presented about the educational level and employment status of caregivers, among other

variables. Data analysis indicated that participants' scores on three factors of the Sensory Profile (Sensation Seeking, Emotionally Reactive, and Inattention/Distractibility) were significantly different than scores of the normative sample, with children in the study demonstrating more behaviors associated with emotional reactivity, sensation seeking, and distractibility.

Care should be taken when interpreting these results in terms of SES because children in this sample also had a variety of mental health diagnoses. Thus, more important to the identification of sensory processing disorders than the demographic characteristics of the sample, low scores of the participants could be related to their mental health conditions. Children from the sample had diagnoses such as Pervasive Developmental Disorders, Disruptive Behavior Disorders, and Communication Disorders. It should be kept in mind that, although this study provides information regarding sensory processing difficulties of a sample of minority children from low socioeconomic status, its purpose was to examine the validity of the Sensory Profile with that particular sample.

Another study examined the prevalence of SMD in a population of minority children enrolled in an urban Head Start program (Reynolds, Shepherd, & Lane, 2008). In the population sampled from the study, 90% of the families were below the poverty line, 80% of the children lived in single-parent homes, and 98% were African American. From that population, 105 families completed the Short Sensory Profile. Findings indicated that 35.2% of the children met the criteria for SMD. A more conservative estimate was made assuming that the total of the non-sampled children ($n = 204$) who

were enrolled in the Head Start program would not meet the criteria for SMD, resulting in 17.6% of children meeting the screening criteria for SMD.

The Short Sensory Profile domains, where differences were identified, were under-responsive/seeks sensation, followed by movement sensitivity, and tactile defensiveness. It was concluded that, compared to previously reported prevalence data, this sample of urban African American children from low income households were two and a half to three times more likely to meet the criteria for SMD. Researchers hypothesized that factors related to fetal development and to exposure to environmental toxins, such as lead, might contribute to higher rates of SMD among minority Head Start children, since these risk factors are more common among low income families.

Lead Exposure: A Risk Factor at the Community Level

Under the Vulnerability Model (Shi & Stevens, 2005), lead exposure can be considered a risk factor at the community level. As such, it is associated with what is referred to in the model as a “predisposing attribute” of a community. Predisposing attributes refer to conditions over which individuals have no direct impact because they are conditions already existent in their geographical, neighborhood, environmental, political and cultural context. Examples are racial/ethnic segregation, pollution, religious, and economic systems. As a risk factor, environmental toxins such as lead exposure influence the context of communities. Gee and Payne-Sturges (2004) suggest that this kind of risk factor might impact particularly disadvantaged communities.

Lead poisoning has been identified as the most important pediatric environmental health problem in the U.S. due to disturbances in the neurological and bodily systems

functions caused by lead. The influence of lead exposure on the behavior of children aged two to five years was studied using a convenience sample of 201 mother-child dyads recruited from the Baltimore Soil Lead Abatement Demonstration Project and from the Kennedy Krieger Institute's Lead Poisoning Referral Center (Sciarillo, Alexander, & Farrell, 1992). Venous samples were collected to determine lead concentrations. Children were divided into two groups: a high exposed group and a low exposed group. The Child Behavior Checklist (CBCL) was used to interview mothers and measure their children's behaviors. Results of the study indicated that, in comparison with the low exposure group, the high exposure group had a significantly higher mean CBCL Total Behavior Problem Score (TBPS). Multiple logistic regression indicated that high-exposed children were 2.7 times more likely to have TBPS in the clinical range. It is interesting to note that, in this study, higher prevalence of behaviors in the high exposed group corresponded to the Aggressive, Somatic problems and Sleep problem scales. While the researchers did not provide a definition of what each of the subscales entail, this information could connect to behavioral manifestations that children with SMD might present. For example, a child might show an aggressive over-response to certain sensory inputs like being touched unexpectedly, or when the usual routine is altered.

Despite observations regarding the socio-demographic characteristics of mothers in the high exposed group, evidence suggesting a direct relationship between socio-demographic variables and blood lead levels is not consistent across studies. An earlier study evaluated how well five sets of variables predicted children's blood lead levels in a sample of middle and upper middle class two year-old children living in metropolitan

Boston (Belinger, Leviton, Rabinowitz, Needleman, & Waternaux, 1986). A longitudinal study was performed in which researchers followed three groups of newborns with widely differing levels of prenatal lead exposure: low prenatal lead exposure (mean 1.8 $\mu\text{g/dL}$), midrange exposure (mean 6.5 $\mu\text{g/dL}$), and high exposure (mean 14.6 $\mu\text{g/dL}$). Data about family characteristics and infant development was also collected during the two years. Findings indicated that, for the group of variables considered (environmental lead sources, mouthing activity, home environment/care giving, prior developmental status, and socio-demographic characteristics), only environmental lead sources and, to a lesser extent, mouthing activity accounted for significant portions of the variance in blood lead levels in a sample of two year old children.

Belinger et al. (1986) stated that “only some of the considered factors are useful predictors of children’s blood lead levels that are relatively high but still within the range presently considered as “safe” (< 25 $\mu\text{g/dL}$). It is important to point out that this study was completed in 1986. The range considered “safe” at that time is not the same now. A “high” blood level is now defined as more than 10 micrograms of lead per deciliter of blood (10 mcg/dL) (Center for Disease Control, 2005).

Indeed, there is evidence that suggest impairments in cognitive functioning, even with lead levels lower than the acceptable limit. A more recent study examined the association between blood lead concentrations assessed throughout early childhood and the IQ of children at six years of age (Jusko, Henderson, Lanphear, Cory-Slechta, Parsons, & Canfield, 2008). One hundred and seventy four children from Rochester, New York, that had previously (at 24 to 30 months of age) participated in a study examining

lead blood levels and dust-control were recruited for this study. In addition to collection of blood samples, the Wechsler Preschool and Primary Scale of Intelligence were administered to the sample of children at the age of six. Information about the children's medical history and demographic information about their families was also collected and considered as covariates. Direct comparisons were made between children with blood lead concentrations $< 5 \mu\text{g/dL}$ with those who had levels $> 5 \mu\text{g/dL}$, but still below the CDC definition of an elevated blood lead level (i.e., 5- 9.9 $\mu\text{g/dL}$). After adjusting for covariates, results showed that childhood blood lead concentrations were inversely related to IQ scores. This pattern was more apparent for the Full Scale and the Performance IQ Scores. In particular, children with blood lead concentrations in the 5- 9.9 $\mu\text{g/dL}$ range had significantly lower IQ scores than children who had concentrations of $< 5 \mu\text{g/dL}$.

Another recent study also examined neurological deficits associated with lead exposure, but at an anatomical level (Cecil, Brubaker, Adler, Dietrich, Altaye, Egelhoff et al., 2008). The relationship between childhood lead exposure and adult brain volume was analyzed using Magnetic Resonance Imaging (MRI). One hundred and fifty seven participants in the Cincinnati Lead Study (CLS), an urban, inner city cohort with detailed prenatal and postnatal histories of low to moderate lead exposure and behavioral outcomes monitored over 25 years, were recruited for this study. Whole brain, three dimensional, high resolution MRI data was used to assess global and regional changes in brain tissue.

Results showed that higher mean childhood blood lead concentrations were associated with region-specific reductions in adult gray matter volume. Considerable portions of the prefrontal cortex presented volume loss including the anterior cingulate cortex (ACC) and the ventrolateral prefrontal cortex (VLPFC). The ACC area processes cognitive and emotional information in separate regions. Functions attributed to the cognitive subdivision include modulating attention and executive functions via sensory and/or response selection. It is also associated with functions related to anticipation of cognitively demanding tasks, error detection, complex motor control, performing new behaviors, and motivation, among other functions. The emotional division is associated with regulation of personal and social behavior, decision making and emotional responses. The VLPFC has also been associated with mood regulation. Cecil et al. (2008) indicate that volume loss in these frontal brain regions is potentially explanatory for cognitive and behavioral problems previously associated with lead exposure which, in general, include intellectual and executive functioning, antisocial behaviors, and attention deficit hyperactivity disorder (ADHD).

Studies using non-human models have looked at brain structures of animals exposed to different amounts of lead. Moreira, Vassilieff, and Vassilieff (2001) measured lead levels in the blood and cerebral regions (hippocampus and striatum) of female rats exposed to lead through drinking water during pregnancy and lactation, and their male pups at 23 (weaned) or 70 days (adult). In dams and 23 day-old pups, exposure to lead (direct for females or indirect prenatal exposure for pups) resulted in higher lead blood concentrations and significant increases in the size of the hippocampus and striatum. In

70 day-old pups, lead was not detected in the blood, but was still significantly increased in the hippocampus and striatum.

Studies about the impact of lead exposure on the nervous system date from before the 80's, as is evidenced in a full review by Finkelstein, Markowitz, and Rosen (1998). Additionally, more recent studies have supported the link between SMD behaviors and neurophysiologic responses to sensation in both typical and diagnostic populations (Mangeot, Miller, McIntosh, McGrath-Clarke, Simon, Hagerman, et al., 2001; McIntosh, Miller, Shyu, & Hagerman, 1999; Reynolds, Lane & Gennings, 2009). If lead exposure is associated with alterations in neurophysiological and brain development (i.e., modulating attention, motivation, regulation of personal and social behavior, and mood regulation, among others), it is possible that lead exposure may be an important risk factor to consider related to SMD. Indeed, evidence from studies using primate models supports this kind of relationship (Schneider, Moore, Gajewski, Laughlin, Larson, Gay, et al., 2007).

Lead Exposure and SMD

No studies thus far have directly examined the relationship between lead exposure and SMD in humans. Evidence for this link, however, has been provided using primate models. An assessment called the Sensory Processing Scale for Monkeys (SPS-M) allowed evaluation of sensory processing in adult rhesus monkeys exposed to prenatal alcohol, stress, or postnatal lead (Schneider, Moore, Gajewski, Laughlin, Larson, Gay, et al., 2007). The SPS-M development was based on a human assessment that measures behavioral responses to a series of tactile stimuli. Researchers randomly assigned rhesus

monkeys born to healthy adult females to study groups. In the lead group, infants were randomly assigned to one of six conditions: no lead, one year of daily lead intake, or two years of daily lead intake, in combination with either chelation therapy or nonchelation treatment beginning at the first year of life. The lead-chelating agent was intended to rapidly lower the blood lead levels of the monkeys assigned to the three chelation therapy groups. These infants were tested with the SPS-M when they were five to seven years of age.

The SPS-M administration entails a series of tactile stimulation items administered by a human experimenter. The first tactile stimulus consists of a feather; the second is a cotton ball; and the third a stiff craft brush. Six trials of each stimulus were administered as a swipe to the cheek and neck area to assess the pattern of responsiveness along trials. Positron emission tomography (PET), a nuclear medicine imaging technique that produces a three-dimensional image or map of functional processes in the body, was also performed with the monkeys.

Findings for the lead experiment indicated that the non-lead exposed groups showed a low and relatively stable response magnitude to the tactile stimuli over trials, whereas the lead-exposed group showed a stronger withdrawal response that increased in magnitude after the first few trials (Schneider's et al., 2007). Chelation therapy modified the lead effect in lead-exposed monkeys such that they did not sensitize to repeated stimulation over trials (Schneider, et al., 2007). According to PET measures, aversive responsiveness was associated with up-regulated striatal dopamine receptor binding. Researchers noted that the striatum (part of the basal ganglia) and the frontal cortex,

jointly referred to as the frontostriatal circuitry, are thought to modulate inhibitory control. The authors mentioned evidence from other studies that suggested disruptions of the circuits involving the basal ganglia and frontal cortex might underlie an array of developmental disorders and possibly play a role in sensory processing disorders, just as their own study indicated.

Another study looked specifically at the impact of lead exposure on tactile defensiveness (Moore, Gajewski, Laughlin, Luck, Larson, & Schneider, 2008). The study followed a similar methodology. Researchers grouped monkeys into the same six experimental conditions and used the SPS-M. As in Schneider's et al. (2007) study, Moore et al. (2008) found that lead-exposed monkeys showed significantly more negative responses to repeated tactile stimuli compared with monkeys not exposed to lead. Also, they found that lead exposure measured during early life (first three months) was positively correlated with the magnitude of the negative response (i.e., the degree of tactile defensiveness).

Individual Risk Factors that will be Considered in this Study

Pre-natal alcohol exposure, pre-natal nicotine exposure, low birth weight and preterm delivery were also considered as risk factors in this study. Applying the concepts included in the Vulnerability Model (Shi & Stevens, 2005), these were named as risk factors at the individual level. Like lead exposure they were considered predisposing characteristics, but at the individual (not at the community) level. Unlike community predisposing attributes, persons may have certain degree of influence over some individual predisposing characteristics such as beliefs systems associated with health

behaviors. However, most of the individual predisposing attributes like demographic characteristics and variables associated with social position (e.g., race, ethnicity, and access to resources) cannot necessarily be controlled. Children cannot control alcohol or nicotine consumption of their mothers during pregnancy (although these are related to health behaviors of their mothers); neither can they control their birth weight or gestational age when born. Thus, these risk factors were labeled as predisposing characteristics.

Prenatal Alcohol Exposure

An analysis of data for 18-44 year-old women from the 2002 Behavioral Risk Factor Surveillance System indicated that approximately 10% of pregnant women in the US used alcohol, and approximately 2% engaged in binge drinking or frequent use of alcohol. The range in individual states fluctuated between 5.4% - 21.6% (CDC, 2004). Minority women such as Latinas are among the groups with higher rates of alcohol consumption during pregnancy (Chambers, Hughes, Meltzer, Wahlgren, Kassem, Larson, et al., 2005). A household survey conducted by the Mental Health and Anti-Addiction Services Administration of Puerto Rico (2002) indicated that 31.8% of females who had been pregnant at some point during the 12 months prior to the study reported that they consumed alcohol during the same period. The sample of the household survey (n = 4322) was representative of all persons 15 to 64 years old in Puerto Rico, not including institutionalized or homeless individuals.

Maternal alcohol use during pregnancy is related to a range of effects in exposed children including hyperactivity, attention problems, learning deficits and problems with

social and emotional development. Adverse effects, especially in regard to the working memory ability of children, have been indicated (Burden, Jacobson, Sokol, & Jacobson, 2005). Specific aspects of attentional function most directly affected by moderate to heavy doses of prenatal alcohol exposure were investigated in a sample of 337 African American children with an average age of 7.5 years. The sample was prospectively recruited between September 1986 and April 1989 during the mother's first prenatal visit to a large urban maternity hospital in Detroit. Mothers were interviewed about their current and at-conception alcohol consumption. Children were assessed using a diverse battery of neuropsychological tests related to four dimensions of attentional function: sustained attention, focused attention, executive function and working memory. The strongest associations between prenatal alcohol exposure and child performance were found for tasks that required working memory through active manipulation of information in memory-related task execution (e.g., digit span).

Prenatal alcohol exposure has also been related to behavioral problems. One study determined that maternal alcohol consumption, even at low levels was related to adverse child behavior (Sood, Delaney-Black, Convington, Nordstorm, Ager, Templin, et al., 2001). The purpose of the study was to evaluate the dose response effect of prenatal alcohol exposure or adverse child behavior outcomes at six to seven years of age. Data collection was made prospectively beginning in 1986 during a screening for alcohol and drug use that was conducted with women attending an urban university-based maternity clinic for their first prenatal visit. Six years later, data was obtained from 501 parent-child dyads using the CBCL in addition to a broad range of other variables (e.g., perinatal

factors of maternal age and education; and post-natal factors like maternal psychopathology, continuing alcohol use, socioeconomic status, blood lead levels in children, among others). For purposes of the study, the average absolute alcohol intake was arbitrarily categorized into no, low (> 0 but < 0.3 fl oz of absolute alcohol per day) and moderate/heavy (≥ 0.3 fl oz of absolute alcohol per day).

Results indicated that increasing prenatal alcohol exposure was associated with lower birth weight and gestational age, higher lead levels, higher maternal age, lower maternal education level, prenatal exposure to other substances, and lower SES. Children with any prenatal alcohol exposure were more likely to have higher CBCL scores on Externalizing (Aggressive and Delinquent) and Internalizing (Anxious/Depressed and Withdrawn) syndrome scales and the total problem scores of the CBCL. Significant differences for Aggressive and Externalizing behaviors were also found among the no and low alcohol groups suggesting adverse effects on child behavior even at low levels of exposure. For Delinquent and Total problem behavior, the difference was significant between the no and moderate/heavy exposure groups, suggesting a higher threshold for these behaviors. After adjusting for covariates, prenatal alcohol exposure remained a significant predictor of problem behaviors in children.

Behavioral deficits associated with pre-natal alcohol exposure are likely due to alterations of structures and functions of the central nervous system. There is evidence that prenatal alcohol exposure compromises serotonin regulation and its thalamocortical afferents in mice. Sari and Zhou (2004) found that fetal alcohol exposure rendered lasting deficits on serotonin and other transmitter systems which may underlie neuropsychiatric

deficits such as those seen in fetal alcohol spectrum disorder. In another study, Powrozek and Zhou (2005) used mice to investigate the role of pre-natal alcohol exposure on the development of the somatosensory cortical barrels, focusing on the postnatal development of the barrels of the posterior medial barrel subfield. “Barrel” is the name used for the cortical representations of the vibrissae (whiskers) of the rat, which form a matrix in which each whisker has its own area of cortex. The development of the sensory cortical barrels is regulated by serotonin-rich thalamocortical afferents. Knowing the effects of prenatal alcohol exposure on serotonin, researchers grouped mice on their embryonic stage into different diet conditions: alcohol, pair-fed, or chow.

Results based on postnatal measures showed that although the overall brain weight and brain volume of the mice was decreased, the area of the posterior medial barrel subfield (defined by serotonin positive thalamocortical afferents and dense cellular aggregation), and the individual barrels within the area were significantly reduced. Researchers indicate that the impact of prenatal alcohol on the general morphological development of the cortical barrels, as well as the decrease in the number of neurons within each individual barrel, suggests a possible functional deficit in the response of the whiskers to sensory stimuli. Findings from this and other studies previously mentioned support the link between prenatal alcohol exposure and central nervous system development and functioning. This has led to studies that look at the association between prenatal alcohol exposure and neurological based disorders such as SMD.

Prenatal Alcohol Exposure and SMD

Prenatal alcohol exposure has been associated with difficulties with social-emotional development and behavioral problems during childhood (Coles et al., 1991; Kelly et al., 2000). There is evidence that children prenatally exposed to alcohol may also display sensory processing problems. A description of the sensory processing and behavior profiles of a sample of children with fetal alcohol spectrum disorders (FASD) is provided by Franklin, Deitz, Jirikowic, and Astley (2008). The researchers conducted a retrospective study using data from 44 children, ages five to ten years, from the Washington State Fetal Alcohol Syndrome Diagnostic and Prevention Network (FASDPN). All the children had received an interdisciplinary diagnostic evaluation, and data with the results of the Short Sensory Profile and the Child Behavior Checklist (CBCL) was available.

SSP results indicated that 32 of the 44 (72.7%) sampled children were classified under the definite difference category. Children who demonstrated deficits in sensory processing abilities also appeared more likely to demonstrate problem behaviors. A negative correlation ($r = -.72$) was found between the results of the SSP (for which lower scores indicate more sensory processing difficulties) and the CBCL (for which higher scores indicate more problem behaviors). Thus, children with FASD who demonstrated sensory processing deficits were more likely to demonstrate functional behavioral deficits. Children with SSP total scores that indicated definite or probable differences had significantly higher scores for the CBCL total problems scores, externalizing problem score, and attention and social problems scale scores. Children with clinical or borderline

CBCL total scores had significantly lower scores for the SSP total score, Under-responsive/seek sensation section scores, and Auditory filtering section scores.

Studies using primate models have also supported the relationship between sensory processing difficulties and prenatal alcohol exposure. Neurobiological correlates of sensory processing disorder and the effects of prenatal alcohol exposure on tactile withdrawal responses (aversion) and habituation to repeated tactile stimulation were investigated by Scheneider, Gajewski, Larson, and Roberts (2008). An existing cohort of prenatal-alcohol-exposed adult rhesus monkeys was used for the study. There were four experimental conditions: prenatal alcohol (mothers that voluntarily consumed 0.6 g/kg alcohol daily), prenatal stress (mothers that experienced a daily ten minute stressor), prenatal alcohol plus prenatal stress, and a control group. The sample of the study consisted of 38 five-to-seven-year-old rhesus monkeys. The SPS-M was administered. Positron emission tomography (PET) was also performed.

Findings showed that the pattern of habituation/sensitization to repeated tactile stimuli differed as a function of treatment group condition. Compared to no exposure to prenatal alcohol, prenatal alcohol exposed monkeys showed a higher overall magnitude of withdrawal response to the feather stimulus. Monkeys who failed to habituate had the highest dopamine-2 like receptor (D_2R) binding availability. Thus, it is suggested that tactile sensitivity could be linked to altered striatal dopaminergic function, which is itself critical for associative learning and attention switching. This can represent an explanation for the findings of the previously presented studies regarding the association between alcohol consumption during pregnancy, cognitive deficits, and slower processing speed

(Burden, Jacobson, & Jacobson, 2005; Burden, Jacobson, Sokol, & Jacobson, 2005).

Based on the results of their study, Schneider et al. (2008) explained that prenatal alcohol exposure could compromise cortical plasticity and therefore, acquisition of adaptive behavioral responses to environmental events.

In addition, exposure to prenatal alcohol and to other teratogens is associated with growth deficiencies during the prenatal period. The causal effect of prenatal alcohol exposure on growth in Fetal Alcohol Syndrome (FAS) has been demonstrated (National Center on Birth Defects and Developmental Disabilities, CDC, & Department of Health and Human Services, 2005). FAS is also related to growth problems during the post-natal period, such as low birth weight, and these growth problems might persist throughout early childhood (Larkby & Day, 1997; National Organization on Fetal Alcohol Syndrome, 2001). It can be conjectured that problems with early growth and development may be related to the development of sensory modulation deficits, as they could reflect a lack of growth in both physical and neurological structures. There is evidence that prenatal nicotine exposure can also lead to low birth weight and premature delivery; therefore this risk factor will also be considered as part of this study.

Prenatal Nicotine Exposure

Studies supporting the association between prenatal nicotine exposure, LBW, and PTD are numerous and the earliest studies date prior to the 1980's (Butler, et al., 1972; Martin & Bracken, 1986; McDonald et al., 1992; Peacock et al., 1998; Spinillo, et al., 1994). Key results of these studies are consistent, indicating that smoking during pregnancy is a risk factor for premature rupture of membranes (PROM) and that the

incidence of premature births is greater for smokers than for non-smokers. In addition, babies born to smokers weigh less, have smaller head circumferences, and tend to be shorter than those born to nonsmokers.

Kramer, Séguin, Lydon, and Goulet (2000) reviewed the evidence on socio-economic disparities in pregnancy outcomes, focusing on disparities in intrauterine growth restriction and preterm birth. They conclude that, “cigarette smoking during pregnancy appears to be the most important mediating factor for intrauterine growth restriction, with low gestational weight gain playing a substantial role.” Interestingly, for preterm birth, cigarette smoking appeared to explain some of the socio-economic disparities.

There are differences in smoking prevalence among nations, ethnic groups within the United States (US), and socio-economic or educational groups (Cnattingius, 2004). For example, from 1974 to 2000, the smallest decline in smoking prevalence among women in the US occurred among those with only a high school education (32% of high school educated women in 1974 smoked vs. 27% who smoked in 2000; compared with 26% of highly educated women who smoked in 1974 vs. 10% in 2000). Similarly, smoking prevalence during pregnancy is highly affected by maternal education. In 2000, 25% of women who attended but did not complete college smoked, vs. 2% of college educated women who reported smoking while pregnant.

Although the CDC (2009) indicates a linear decrease in smoking habits from 1998-2007 in 28 states, Washington DC, and PR, it is estimated that cigarette smoking results

in \$193 billion in direct health-care expenditures. Some of those expenditures are related to the reproductive effects of prenatal nicotine exposure (CDC, 2009).

More current studies have examined the association between smoking in pregnancy and behavior of children. The incidence of externalizing behavior problems among 18-month-old children after prenatal nicotine exposure was examined using data from a population-based study (Stene-Larsen, Borge, & Vollrath, 2009). Results indicated that maternal smoking during pregnancy increased children's risk for externalizing behaviors problems, especially if the mother smoked at least 10 cigarettes per day. This was true even after adjusting for confounding variables like gender, gestational age when born, birth weight, and single parent status.

As of 2011, no study had looked at nicotine exposure and SMD. For this reason, prenatal nicotine exposure has been included in this study as an important variable related not necessarily with SMD, but specifically with low birth weight and preterm delivery.

Low Birth Weight and Preterm Delivery

Babies born in the US are more likely to have low birth weight (LBW) than those born in almost every other developed country (Reichman, 2005). Low birth weight and premature children are at elevated risk for debilitating medical conditions and learning disorders. Birth weight is defined as very low (VLBW), less than 1500 grams, or about 3.3 pounds), low (LBW-less than 2500 grams), or normal (NBW- 2500 grams or more, or about 5.5 pounds) (CDC, 2002). A premature or preterm birth is a birth that occurs at least three weeks before a baby's due date (or less than 37 weeks — full term is about 40 weeks) (CDC, 2007). Although low birth weight and preterm delivery are strongly related

and frequently studied together, one might not necessarily imply the other; thus the importance of looking at them separately in this study.

During 1990 infants born in PR were 1.03 times more likely to be of LBW than US (mainland) born infants. From 1990 to 2000, the LBW rate for Puerto Rican newborns increased 18.0% (from 9.2% to 10.9%), while for mainland newborns, the LBW rate increased 3.7% (8.9% to 9.3%) (CDC, 2003). Percentages of LBW infants on the island in 2000 fluctuated between 6.12% in the municipality of Florida, and 21.5% in the municipality of Maricao (National Council of La Raza, 2004). There were 522,913 preterm births in the US during 2005, 12.7% of live births (March of Dimes Foundation, 2008). During 2005, 9,978 babies were born preterm in PR, 19.7% of live births. It is calculated that in an average week in PR 975 babies are born; 192 are preterm infants and 125 are LBW (March of Dimes Foundation, 2008).

Evidence suggests that low birth weight can have significant and, indeed, lasting effects. According to a study that included a nationally representative sample of the United States population (by using existent data from the Panel Study of Income Dynamics, University of Michigan), birth weight, adult health and socioeconomic success are linked (Johnson & Schoeni, 2007). Compared to their normal weight siblings, low birth weight children in this study were 30 percent less likely to be in excellent or very good health in childhood. Also, they scored significantly lower on reading, comprehension, and math achievement tests. Low birth weight subjects were one third more likely to drop out of high school relative to other children and more than 70 percent of them were in fair or poor health as adults. The study's findings suggest that low birth

weight is a risk factor that impacts disadvantaged populations, which increases the probability of undesired developmental outcomes. In addition, the findings support the results of previous studies that have looked at educational and behavioral outcomes in association to low birth weight.

Klebanov, Brooks-Gunn, and McCormick (1994) compared children with extremely low birth weight (ELBW- children weighed ≤ 1000 grams at birth), with very low birth weight (VLBW- 1001-1500 grams at birth), with heavy low birth weight (HLBW- 1500-2500 grams at birth), and normal birth weight (NBW- >2500 grams at birth) on a series of indicators of school achievement that included grade failure, placement in special classes, classification as handicapped, and math and reading achievement scores. Data for the study was obtained from a cohort of children ($n = 1868$) who participated in two previous studies in which prospective collection of data was made from the newborn period. Most of the participants were born between April 1, 1979 and March, 31 1981. Results indicated that as birth weight decreased, the prevalence of grade failure, placement in special classes, and classification as handicapped increased even after controlling for maternal education and neonatal stay. ELBW children scored lower than all other groups on math and reading achievement tests. Even those among them with IQ scores above 85 obtained lower math scores than NBW children. Researchers indicated that such findings suggest the potential for future educational needs for LBW children. Results of these studies are consistent with the ones found by Rose and Feldman (2000) in which preterm and LBW children evaluated at the age of

eleven demonstrated lower performance on specific cognitive abilities when compared with their full-term mates.

Data from the same cohort was used to examine the relationship between birth weight and classroom behavior based on teachers' reports (Klebanov, Brooks-Gunn, & McCormick, 1994). For this study the sample was of 1120 children with a mean age of 9.16 years. Reports from teachers included information regarding children's language and attention in the classroom, behavior problems and social competence. Children were classified into four groups: ELBW (≤ 1000 grams at birth), other very low birth weight (OVLBW- 1001 to 1500 grams at birth), HLBW (1501-2500 grams at birth), and normal weight (>2500 grams at birth).

Results indicated that, even when controlling for neonatal stay, gender, ethnicity, and maternal education, the ELBW children had poorer attention and language skills, lower overall social competence, and poorer athletic and scholastic competence than all other birth weight groups. Also, all LBW children had lower attention and language skills and scholastic competence and higher daydreaming and hyperactivity than NBW children. ELBW children had higher scores for daydreaming and were rated as more hyperactive than NBW children. They were also rated as less socially and athletically competent. Classroom behavior of LBW children was rated by teachers as poor, even for children who had not failed a grade. Klebanov et al. (1994) concluded that as birth weight decreases, the magnitude of behavioral, social, and attention and language problems exhibited in elementary school classrooms increase.

Behavior of younger children has also been examined in association with preterm delivery. A prospective cohort study determined behavioral outcomes and risk factors for abnormal behavior in preterm infants born before 32 weeks (Stoelhorst, Martens, Rijken, Zwieten, Zwinderman, & Veen, 2003). Participants were two year old (corrected age) Dutch children born between 1996/1997, registered in the Leiden Follow-up Project on Prematurity. Findings showed that parental perception of the behavior of children in the cohort was favorable and problem scores in the clinical range on the Child Behavior Checklist were comparable to that of a general population sample. However, preterm children scored higher than children from the general population on the somatic problems scale. By the same token, those born small for gestational age (i.e., babies whose weight was below the 10th percentile for that gestational age) were among those with higher scores for anxious/depressed and/or withdrawn behavior.

The results of the Stoelhorst, et al. (2003) study are, to some extent, consistent with the findings of other studies performed with older children. Tessier, Nadeau, and Boivin (1997) examined the social dimensions of behavior in two studies. Their purpose was to compare the social behavior of school age children born prematurely and/or LBW, with that of children born as healthy full-term infants. One hundred and forty seven 11-year-old children (of whom 49 were reported by their parents to have been born prematurely) participated in Study One; 84 boys of the same age, 28 of whom were born with a birth weight less than 2000 grams, were the participants of Study Two. Children and teachers selected for Study One were part of a more extensive research project that included sociometric measures, peer reports and teacher ratings. Data for Study Two was

obtained from a longitudinal study undertaken with children attending schools located in underprivileged social and economic environments. For both studies, peer and teacher ratings were used to evaluate the possible social and behavioral outcomes of preterm and/or LBW children.

Three factors resulted from the principal component analysis performed with the data from Study One to reduce the number of dimensions characterizing the Peer Revised Class Play and Peer Nomination Inventory (questionnaires completed by children to evaluate their peers' behavior). Resulting factors were: internalization (verbal and physical victimization, and active and passive withdrawal), externalization (aggressivity scores), and sociability. A different instrument, the Pupil Evaluation Inventory (PEI) was used in study two. Principal component analysis to reduce the quantity of dimensions characterizing the PEI resulted in three dimensions: internalization (withdrawal), externalization (agressivity), and a likeability score.

In both studies, scores obtained from peer evaluations and teacher ratings suggested that there was no relationship linking prematurity or LBW to aggressive or externalized behaviors. Peer and teacher assessments indicated a greater level of social withdrawal for preterm/ LBW children. Researchers were not able to confirm their hypothesis that preterm and/or LBW children were, at 11 to 12 years, deemed by their peers to exhibit less pro-social behavior than healthy and full-term children. However, findings of both studies suggested that preterm LBW infants were more internalized and withdrawn than full term subjects. According to Tessier et al. (1997), internalization can be a marker of suboptimal social functioning of these children. It is possible that the

behavioral characteristics of children with internalized behaviors may be consistent with those shown by some children with SMD, as described in the section “Sensory Modulation Disorder,” at the beginning of this chapter.

Low Birth Weight, Preterm Delivery, and SMD

In another study, sensory responsiveness in preterm and full term infants was compared, and the relationship of sensory responsiveness to temperament and developmental function was examined (Case-Smith, Butcher, & Reed, 1998). A sample of 45 preterm infants who spent at least two weeks in the NICU at Children’s Hospital in Columbus, Ohio, participated in this study. Twenty two additional full-term infants, matched for age, were recruited to compare sensory responsiveness. The Sensory Rating Scale (a questionnaire for the primary caregiver) was used to evaluate sensory responsiveness. The Bayley Scales of Infant Development (BSID-II) was used to measure mental and motor development in the preterm sample.

Results of the study indicated that preterm infants exhibited more frequent behaviors indicating tactile defensiveness and difficult temperament than did the full term infants. Examination of specific items also showed that preterm infants displayed more sensory seeking behaviors and higher activity levels compared to full-term infants. Sensory responsiveness was not related to BSID-II mental and psychomotor scale scores. However, based on information provided by caregivers’ on the Sensory Rating Scale, sensory responsiveness was significantly related to temperament.

More recent evidence also suggests the presence of possible sensory modulation issues in preterm and low birth weight infants. Weiss (2005) noted that infants born

prematurely are deprived of typical patterns of tactile and vestibular (movement) stimulation that are normally available during prenatal development. In addition these infants are often hospitalized for weeks after birth because of their medical complications. Thus, the touch they receive is related primarily to medical care given, with minimal exposure to socio-emotional touch, which is a normative experience for most newborns. As a result, the haptic experiences of these infants may influence their psychosocial and physiological development in unique ways (Weiss, 2005). Putting Weiss' explanations into the sensory integration framework, it might be said that early experiences of preterm and low birth weight infants could alter the developing CNS, impacting their ability to produce purposeful or adaptive responses to environmental demands.

Findings of another study are in line with Weiss' (2005) rationale. Researchers from the United Kingdom conducted quantitative sensory testing on extremely preterm children (born less than 26 weeks gestation) to investigate persistent alterations in sensory perception (Walker, Franck, Fitzgerald, Myles, Stocks, & Marlow, 2009). Participants included 43 children, 11 years of age, from the EPICure cohort (children born less than 26 weeks of gestation in 1995). Thermal and mechanical tests were performed on the thenar eminence of the non-dominant hand, and on skin of normal appearance adjacent to scar sites related to neonatal interventions (e.g., neonatal thoracotomy scars and scars related to other less invasive procedures). Thermal stimulation was provided to sequentially determine the perception thresholds of the children to different temperatures: cool, warm, cold, and hot. Mechanical detection

thresholds were determined using standard (von Frey) filament hairs at slightly different sites within a small area to avoid habituation. Participants kept their eyes closed and reported when they felt the filament touching their skin. Results indicated that, when compared to term-born children, preterm children presented generalized changes in thermal sensitivity (including a decrease in thermal sensitivity), but not in mechanical sensitivity.

Additional studies have emphasized the importance of sensory stimulation, especially tactile stimulation, for preterm children (Feldman & Eidelman, 2003; Mathai, Fernández, Mondkar, & Kanbur, 2001). Feldman and Eidelman (2003) indicate that tactile stimulation through skin to skin contact (or Kangaroo care) accelerates autonomic and neurobehavioral maturation in preterm infants during their stay in the NICU. The researchers examined responses of two groups of 35 preterm infants matched by sex, birth-weight, and gestational age, among other variables. One group received Kangaroo care and the other did not. Infants receiving Kangaroo care showed more rapid maturation of vagal tone (i.e., impulses from the vagus nerve producing inhibition of the heartbeat), and more rapid improvement in state organization (in terms of longer periods of quiet sleep and alert wakefulness). Also, neurodevelopmental profiles of these children were more mature, particularly in terms of habituation and orientation. Findings like the ones presented here link behavioral and physiological responses to sensory stimuli and to central nervous system processes, thus allowing hypotheses regarding a possible relationship between SMD, low birth weight and preterm delivery.

Summary

This literature review has presented information regarding the theories guiding this study, each of the risk factors of interest, and their impact on developmental outcomes and SMD. This study was intended to examine the prevalence of SMD in a sample of Puerto Rican preschoolers from high and low SES.

As of 2011, no studies were found that determined the prevalence of SMD in Puerto Rico, nor that relate differences in exposure to risk factors between children from diverse SES backgrounds. An additional purpose of this study was to examine relationships between the identified risk factors and SMD. Relationships between the variables of interest were hypothesized based on the reviewed literature. Figure 5 illustrates the hypothesized associations.

As stated in the Vulnerability Model (Shi & Stevens, 2005), SES is an enabling characteristic (i.e., a resource available to overcome the consequences of vulnerability) that typically makes groups more susceptible to risk factors. Research supports the conclusion that the incidence of prenatal alcohol exposure, pregnancy smoking, and lead exposure is greater among groups from low SES. Therefore, two double headed arrows are used to represent the bidirectional relationship between these variables. In addition, pre-natal alcohol and nicotine exposure can impact birth weight and gestational age of the child when born. Except for smoking during pregnancy, previous studies have examined the other risk factors (i.e., SES, pre-natal alcohol exposure, lead exposure, low birth weight, and preterm delivery) separately in association to SMD. However, this study

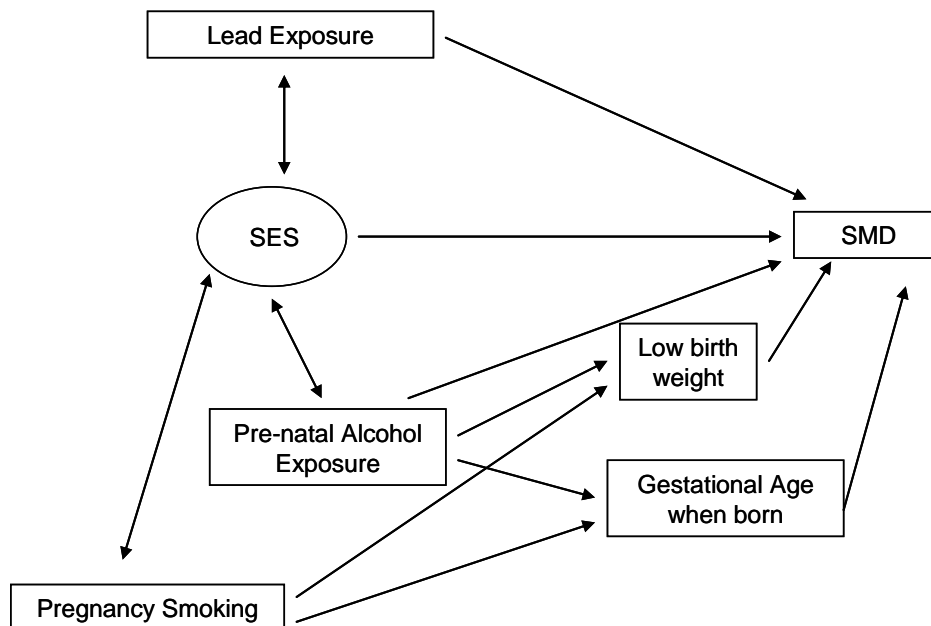


Figure 5. Relationships Among the Variables Included in this Study

entailed an initial exploratory effort including all of them together; thus considering health disparities in the understanding of SMD.

Specific Aims and Hypotheses

As stated in the Introduction, there were three specific aims for this study. They are presented below with their respective hypotheses.

1. To establish the presence and examine the prevalence of SMD in a sample of PR preschoolers from different SES backgrounds.
 - a. It was hypothesized that prevalence rates determined in this study would be higher than those reported in previous research with children from the US mainland.

- b. It was hypothesized that SMD (indicated by total scores of the SSP) would be higher among preschoolers whose caregivers have lower educational degrees and lower household incomes.
- 2. To determine if relationships between sensory modulation and the identified risk factors could be explained by an exploratory path analysis model. Figure 5 in Chapter Two presents a diagram that illustrates the hypotheses related to this aim.
 - a. It was hypothesized that moderate relationships between SES and prenatal alcohol exposure, SES and prenatal nicotine exposure, and SES and lead exposure would be observed.
 - b. It was hypothesized that SES and prenatal alcohol exposure would be the variables with the higher directional linear associations with SMD (as long as lead exposure is not considered as part of the analysis).
- 3. To explore changes in the relationships between sensory modulation and the identified risk factors when the variable lead exposure is included as an additional risk factor in a second exploratory path analysis model for a part of the sample.
 - a. It was hypothesized that, once lead exposure is included as part of the analysis, SES and lead exposure would be the variables with the higher directional linear associations with SMD.

Procedures and particular strategies used to examine each of these specific aims and hypotheses are described in the forthcoming chapter.

CHAPTER III

Methodology

Design

In order to achieve the aims of this study, a non-experimental descriptive design was used. The purpose of descriptive studies is to observe, describe, and document aspects of a situation as it naturally occurs (Polit & Beck, 2008). In this case, the descriptive design was used to examine differences regarding risk factors and Sensory Modulation Disorder (SMD) among children from different socio-economic status (SES) backgrounds. Descriptive designs include correlational studies, the aims of which are to describe relationships among variables rather than infer cause and effect relationships (Polit & Beck, 2008). One of the purposes of this study was to examine the relationship between identified risk factors and prevalence of SMD for the participants. Thus, the purposes of this study are consistent with a non-experimental descriptive correlational design (Polit & Beck, 2008).

Measures

Demographic and Risk Factors Data Sheet

A Demographic and Risk Factors Data Sheet was used to ask caregivers about exposure to five of the risk factors of interest: SES (measured by household income and caregivers' highest educational degree), prenatal exposure to alcohol, birth weight and

gestational age at the time of delivery. Appendix A presents the English and Spanish versions of that document.

Risk factors included in the Demographic and Risk Factors Data Sheet were collected as follows:

1. Socioeconomic status – Income and education, the most commonly used measures of SES in the United States (Braverman, et al., 2005), were the two dimensions used for measuring SES in this research study. Household income was classified using the following ranges:

- \$14,999 or less
- \$15,000 - \$24,999
- \$25,000 – \$34,999
- \$35,000- \$49,999
- \$50,000 – \$74,999
- \$75,000 – \$99,999
- \$100,000 - \$149,999
- \$150,000 or more

These classifications are the same used for the last community survey of the Census Bureau in PR (2008), with the first and last two ranges merged (i.e., first two ranges in the Community Survey were: “less than \$10,000” and “\$10,000 - \$14,999”; last two ranges were: “\$150,000 - \$199,000” and “more than \$200,000”). These ranges were narrow enough to provide needed descriptive information about SES of participants.

However, for purposes of some of the analyses performed (e.g., MANOVA), additional ranges were merged.

Educational degree was also classified using ranges from the last Census Bureau Community Survey:

- 8th grade or less
- 9th – 12th (no high school diploma)
- Graduated from high school or equivalent program
- Some college courses (degree not completed)
- Certificate
- Associate degree
- Bachelors degree
- Graduate degree.

The highest educational level reached by any primary caregiver with whom the child lived was the variable score considered in the analyses. Mentioned ranges allowed more specific descriptions of participants, although merging was used in order to comply with assumptions of some of the analyses performed (e.g., MANOVA).

2. Pre-natal alcohol exposure – Participants were asked to select which of the following categories better described their pattern of alcohol consumption during pregnancy:

- Every day
- Nearly every day
- Three to four times a week

- Two times a week
- Once a week
- Two to three times a month
- Once a month
- A few scattered occasions during pregnancy
- Never

These categories are the same used for the 2001 National Epidemiologic Survey on Alcohol and Related Conditions (NESARC). Additionally, the Center for Disease Control's definition of binge drinking (having at least five drinks on any one occasion during the previous 30 days) was used as a guide to get some information about the quantity of alcohol consumption of participants. This study replicated the methods used by other researchers (Tsai, et al., 2007; Dawson, 2003) by asking research subjects if they had more than five drinks on any one occasion during pregnancy (considering all types of alcoholic beverages, i.e., beer, wine, cordials, etc.). Although this information was not included as part of the statistical analyses, it was considered useful for purposes of sample description.

3. Birth weight and gestational age at the time of delivery - Birth weight was measured using the categories defined by the Center for Disease Control (CDC, 2002): less than 3.3 pounds (Very low birth weight), 3.4 – 5.5 pounds (low birth weight), and more than 5.5 pounds (normal birth weight). To determine if children were born preterm, caregivers were asked if their child was born before 37 weeks of gestation, which corresponds to the CDC's (2002) definition of a preterm child. An option of "Other;

please comment...” was offered to help reduce the occurrence of missing data or inaccurate reporting.

4. Pre-natal nicotine exposure –No studies have been found relating pre-natal nicotine exposure to SMD. However, evidence indicates that smoking during pregnancy is related to low birth weight and pre-term delivery (Cnattingius, 2003; Kramer, Séguin, Lydon, & Goulet, 2000; Peacock et al., 1998). Thus, this variable was measured because of its potential covariance effect. Participants were asked how many cigarettes they smoked during pregnancy on an average day. Categories used to classify participants’ responses were based on the ones used by Jacqz-Aigrain, et al., (2002):

- Over 20 cigarettes per day (more than a pack)
- 11-20 cigarettes per day (more than half a pack)
- 1-10 cigarettes per day (half a pack or less)
- None (0 cigarettes)

Measure of Lead Exposure

Blood lead levels were measured in µg/dL and collected only from Head Start preschoolers. Federal law requires states to screen children enrolled in Medicaid for elevated blood lead levels as part of prevention services provided through the Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) program (CDC, 2000). Since 1998, federal Medicaid regulations indicate that all children aged 36-72 months who have not previously been screened must receive a blood lead test. This test is the only screening element (Knipper, 2004) required in order to early diagnose and treat any health problem associated with elevated blood lead levels before it becomes more

complex. Specific follow-up care procedures are established for children identified at risk of lead poisoning. Due to this regulation, Head Starts in Puerto Rico ask for a blood lead test as part of the admission procedures.

Contacts were made with directors of Head Start districts at the municipalities of Toa Baja and Vieques. With consent from the children's caregivers, Head Start districts provided access to the results from the blood tests of the children. However, at the time of data collection for this study, some parents had not yet arranged to have blood lead tests given to their children. Special attention to this matter was necessary during the data analysis process. Measures taken are discussed in Chapter Four. In addition, the use of retrospective data to get this measure, as well as the type of biomarker used for the measure (blood), entailed other limitations in terms of the reliability of the data that were not possible to overcome, due to the scope and resources available for this study. These limitations are discussed in Chapter Five.

Short Sensory Profile

The Short Sensory Profile (SSP), in its Spanish version, was used to collect data regarding the prevalence of SMD. The Short Sensory Profile (SSP), a condensed version of the Sensory Profile (SP) is a 38 item questionnaire that examines the behavioral responses of children to sensations of daily life events. The purpose of the development of the SSP was to provide a short caregiver questionnaire that measures sensory modulation during daily life and could be easily incorporated into screening processes or research projects (McIntosh, Miller, Shyu, & Dunn, 1999).

Each of the items on the SSP asks caregivers to indicate the frequency with which a particular behavior is observed. For example, to determine expression of distress during grooming, an item such as “*fights or cries during haircut, face washing, fingernail cutting*” is used. A five-level frequency scale is provided for each item for the caregiver to report if the behavior is observed: always (100% of the time), frequently (75% of the time), occasionally (50% of the time), seldom (25% of the time), or never (0% of the time). The questionnaire provides a total score and a score for each of its seven sections:

1. Tactile sensitivity
2. Taste/smell sensitivity
3. Movement sensitivity
4. Under-responsive/seeking sensation
5. Auditory filtering
6. Low energy/weak
7. Visual/auditory sensitivity.

Results of the SSP allow classification of child performance into categories of typical performance, probable difference or definite difference; this classification is used for total scores as well as for section scores. According to McIntosh et al. (1999), the most important score of the SSP is the total score. A total score in the definite difference range indicates that the child does not process sensory information in a way that facilitates an adequate interaction with the environment. However, a definite difference on any of the sections should be cause for concern (McIntosh, et al., 1999).

The SSP was developed using the items of the original Sensory Profile that best fit with the theoretical construct of sensory modulation and those that, as reflected through principal components factor analysis, better loaded on the resulting sections. The national sample of 1,037 children without disabilities used to develop the Sensory Profile was used to perform the final principal components analysis that confirmed the structure of the SSP. Cronbach's Alpha reliability coefficients were estimated for the test total and for sections using a smaller sample of 117 children with typical development and with different diagnoses (like Fragile X Syndrome or other developmental disabilities). All reliability coefficients ranged from .70 to .90. The reliability coefficient calculated with the sample of this study (Cronbach's Alpha = .74) is consistent with values reported in the tool's manual.

Inter-correlations of the SSP total and section scores, which were low to moderate (rated between .25 to .76), indicate that the sections measure unique aspects of sensory modulation (McIntosh et al., 1999). This, in conjunction with conceptual relationships among the sections of the SSP and factors of the long version of the Sensory Profile, supports the instrument's internal validity. Other studies have supported construct validity of the SSP by evidencing atypical physiological responses to sensation (electrodermal responses) of children whose parents reported behavioral responses to sensations in one of the initial research versions of the SSP (McIntosh, Miller, Shyu, & Hangerman, 1999).

Evidence has also supported the tool's validity based on relations to other variables, as defined in the Standards for Educational and Psychological Testing

(American Educational Research Association-AERA-, American Psychological Association-APA-, & National Council on Measurement in Education-NCME, 1999). These Standards indicate that categorical variables, including group membership, become relevant as “evidence of validity based on relations to other variables” (p.13), when the theory underlying a proposed test suggest that group differences should be present or absent if a proposed test interpretation is to be supported. Mangeot and colleagues (2001) used the SSP to compare the occurrence of sensory modulation dysfunction of 26 children with ADHD and 30 typically developing children between five and 13 years of age. Children with ADHD presented significantly lower scores on six of the seven subscales of the SSP: sensory seeking, auditory filtering, and sensitivity to tactile, auditory, visual, and taste and olfactory stimuli. Findings imply that observed relationships are consistent with the construct underlying the proposed interpretations, thus supporting validity based on relations to other variables.

Information provided by Winnie Dunn (email communication, July 30, 2008), indicate that the SSP was translated to Spanish using a “typical back translation process.” According to Nancy Castilleja, product line manager of Pearson Inc., there have been no published studies conducted with the Spanish Sensory Profile to verify reliability and validity (email communication, July 30, 2008). A back translation process involves the translation from English to Spanish by a translator; and the translation of the resultant tool from Spanish to English by a second translator. The back translated version is compared with the original one and modified as needed in order to achieve accuracy with that original English version (McKay, Breslow, Sangster, Gabbard, Reynolds, Nakamoto,

et al., 1996). Given language differences among Spanish speakers, strategies (included in the “Procedures” section) were applied to avoid confusion among participants when completing the SSP questionnaire.

Population and Sample

The target population for this study was Puerto Rican preschoolers. A group of caregivers and their children from low SES areas (n= 78) was recruited from Head Start Programs located at Toa Baja and Vieques. A group of caregivers and children from high SES areas (n= 63) was recruited from private preschools located at Guaynabo. Quantity of participants per municipality and municipalities’ characteristics are summarized in Table 1.

As stated in Table 1, data was collected from a total of 141 subjects recruited through convenience sampling. Sample size, initially proposed based on power analysis and following suggested guidelines in the literature, was 120 subjects (final sample size had 21 additional participants). For example, an *a priori* alpha level of .05 was set, considering values conventionally used (Rossi, Lipsey, & Freeman, 2004). Based on previous work by Reynolds and colleagues (2008), an effect size of .60 was estimated to calculate the needed sample size. According to Cohen’s general guides, such effect size value is considered as a medium effect (Cohen, 1988, in Wilson Van Voorhis, & Morgan, 2007). The online available application called “WebPower” (<http://www.math.yorku.ca/SCS/Online/power/>) was used to complete power analysis.

According to the analysis, a sample of 6 subjects per cell (if equally distributed among nine cells) and an effect size of .60 corresponded to a statistical power of .80,

Table 1

Characteristics of Municipalities and Number (N) of Participants

Municipality	(N)	Characteristics/reason for selection
Vieques	30 from low SES	<ul style="list-style-type: none"> - Exposure of Vieques's residents to environmental lead, associated to previous US military practices in the area that have been documented (Massol-Deyá, Pérez, Pérez, Berríos, & Díaz, 2005; Ortiz- Roque, Ortiz-Roque, & Albandoz- Ortiz, 2000). - More than 50% of children at Vieques live in poverty (National Council of La Raza, 2004).
Toa Baja	48 from low SES	<ul style="list-style-type: none"> - This municipality is geographically and demographically similar to Guaynabo. - Percentage of children living in poverty is near the percentage of children living in poverty at Guaynabo (49% at Toa Baja – National Council of La Raza, 2004).
Guaynabo	63 from high SES	<ul style="list-style-type: none"> - Guaynabo is the municipality with the lowest percentage of children living in poverty in PR (42%- National Council of La Raza, 2004).
Total	141	<ul style="list-style-type: none"> - All municipalities are near/accessible to the municipality where the researcher resides (San Juan).

which is in accordance to the conventionally used value (Rossi, Lipsey, & Freeman, 2004). Other guidelines supported the use of the proposed sample size for purposes of other statistical analyses (e.g., structural equation modeling, Bentler & Yuan, 1999). Discussion about results obtained with the final sample size of the study and limitations found are available in Chapters Four and Five.

Information was gathered about children diagnoses, if any, in the “Demographic and Risk Factor Data Sheet.” Caregivers of children with severe motor impairments (i.e., those caused by neurological conditions such as cerebral palsy or spina bifida) were excluded from the sample because motor impairments might impact a child's

performance on some items included on the Short Sensory Profile (e.g., item 5- Withdraws from splashing water; item 10- Limits self to particular food textures/temperatures; item 31- Can't lift heavy objects). However, no children in the participant preschools had any severe motor impairment, and therefore no children were excluded for this reason. Additionally, caregivers were asked to indicate if their child had any Pervasive Developmental Disorder (PDD) and Attention Deficit Hyperactivity Disorder (ADD/ADHD), among other conditions (see “Demographic and Risk Factors Data Sheet” in Appendix A). Two participants had diagnoses of PDD and two other had been diagnosed with ADD/ADHD. Children with these diagnoses were included for purposes of the first research aim (i.e., prevalence of SMD). However, due to the documented incidence of sensory modulation issues in children with these diagnoses, they were excluded for purposes of the second and third research aims (i.e., relationship between sensory modulation and risk factor variables examined through a path analysis model).

Procedures

Strategies Applied Prior to the Beginning of the Study

No studies have been conducted to assess reliability or validity of the Spanish Sensory Profile (neither of the Spanish Short Sensory Profile). However, literature indicates that all survey questions should be “tested to make sure that they work for the populations, context, and goals of a particular study” (Fowler, 2002, p. 107). Cognitive interviews provide a first step towards this aim. They entail a strategy to study the

manner in which targeted audiences understand, mentally process, and respond to the materials presented (in this case, the Spanish Short Sensory Profile) (Willis, 2005).

Fowler (2002) states that the purpose of a cognitive interview is to find out if people are consistently able to understand questions as they appear on a measurement tool. In order to improve the quality of this study and ensure questions were valid for PR caregivers, eight cognitive interviews were conducted prior to formal data collection, with mothers of children between three to five years old using the Spanish Short Sensory Profile. Four mothers were from Head Start and four were from private preschools; they had different educational backgrounds and household incomes. During the same interview process, participants' understanding of questions in the "Demographic and Risk Factor Data Sheet," developed for use in this study, was also tested through the cognitive interviews.

Retrospective verbal probing was the technique used during the interviews. When this technique is employed, subjects are asked probe questions after the questionnaire has been administered (Willis, 2005). Participants were asked to communicate questions, doubts, or suggestions to make the SSP more understandable. Also, as suggested by Fowler (2002), the respondents were asked to say in their own words what they think each of the SSP and "Demographic and Risk Factor Data Sheet" questions were asking. Examples of such questions are: How do you interpret what the item is asking?; What are some examples of your child's behavior that made you choose that answer?; and What changes, if any, would you make to the item to improve its understanding? In addition, spontaneous probes, which emerged during the interview, were also used.

Overall, the Short Sensory Profile was found to be a useful tool when administered to the participant sample of Puerto Rican caregivers (Román-Oyola & Reynolds, 2010). They expressed some doubts and concerns related to their understanding of the content of some particular items (rather than with language issues). Thus, a supplemental form was developed for clarification of items which required additional explanation. This form is included in Appendix B and was included with the Short Sensory Profile as part of the subjects' packages in an effort to enhance the accuracy of their responses and, thus, the reliability of this study's results.

Study Procedures

The procedures of this study were performed as described in the following phases:

Phase I (IRB approval): This proposal was submitted and approved by the Virginia Commonwealth University Institutional Review Board (IRB).

Phase II. Initial Contact: Directors of Head Starts located in the municipalities of Vieques and Toa Baja were contacted, as well as directors of private preschools in Guaynabo. A brief explanation about the study was provided. Directors who demonstrated interest in collaborating in the study were visited for a more detailed orientation. A one hour conference open to preschool personnel and parents was held at each preschool. The purpose of the conference was to provide information related to the background of the study including information about: (1) What is sensory modulation and the ways it can impact children's occupational performance; (2) The purposes of the study and its importance; (3) The way in which school personnel and parents can collaborate with the study. In addition, conferences provided an opportunity to clarify any

doubts or questions regarding what was entailed in the study. By providing the orientation, preschool personnel and parents were able to communicate with the researcher about the purposes and pertinence of the study. Also, orientations helped to emphasize awareness about the importance of providing honest information to enhance reliability of results of the study.

Phase III. Recruitment: After the orientation at the preschools, survey packages were given to collaborating teachers to give to the parents of preschoolers. Packages included: (1) consent form (See Appendixes C and D), (2) a Spanish version of the SSP, (3) a “Demographic and Risk Factors Data Sheet” (See Appendix A), (4) written guide with clarifications for possible doubts about the questionnaires (See Appendix B), (5) a separate form for parents to provide their name and postal address *only* if they were interested in receiving a mailed summary with the results of the SSP and a \$10 gift card (mailed to those interested as compensation for their participation) (See Appendix E), and (6) an additional envelope. Each envelope had a numeric code at the upper right corner. Parents who consented to participate completed the surveys (SSP and “Demographic and Risk Factors Data Sheet”) filled out the consent form, put the three documents (consent form and the two questionnaires), and the sheet with their postal address (if applicable) inside the envelope, sealed it, and deposited the envelope in a locked mailbox placed by the researcher (with authorization of the teacher) in the children’s classroom. The mailboxes were placed in the classrooms for three weeks. The researcher visited the classrooms twice a week, early in the morning (when parents brought children to the classroom) or during the afternoon (when parents picked up their children at classroom),

to personally give postcard reminders to parents and provide them additional opportunities to ask questions or clarify doubts. Three weeks after the researcher's visit, gift cards were sent to participants who requested them by completing the form in Appendix E. To avoid the inconvenience to caregivers of having to fill out two packages in cases where there were siblings attending the same preschool, teachers were asked if there were any siblings in the classrooms. Only one case was identified at Toa Baja. The researcher flipped a coin to randomly determine that data would be collected about the younger sibling. This procedure, as well as the others described in this section, were detailed in the consent form (see Appendix C).

A response rate of 64% was obtained. Table 2 indicates the sample size from each municipality and the quantity of packages sent to parents.

Table 2

Sample Sizes from Each Municipality and Response Rate

Municipality	Sample size	Packages sent	Response rate (%)
Vieques	30	50	60
Toa Baja	48	70	69
Guaynabo	63	100	63
Total	141	221	64

The total response rate was higher than expected (30%). Three principal factors apparently contributed to this higher rate: (1) Consistent follow up by the researcher who visited the preschools twice a week; (2) Interest in the theme of the study from the preschools' teachers; and (3) use of incentives for participants (results of the children's performance on the SSP and \$10 gift card). The final sample included children who

participated from one Head Start program at Vieques, two Head Starts centers in Toa Baja, and two private preschools in Guaynabo.

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Phase IV. Collection of blood lead levels data: After three weeks spent collecting the questionnaires, a single date was scheduled with the Head Start directors for collection of the children's blood lead levels. Three days prior to the collection date, a list of the children whose parents gave permission to researchers to obtain blood lead levels from their records was given to the directors. The list included the child's last and second last names with the first initial. This allowed Head Start personnel to have a clear idea about the records the researcher would be reviewing and to take any pertinent action (e.g., make available the records of appropriate subjects for the scheduled date) to provide access to the information. On the scheduled day, the directors assigned a person from the Head Start program to accompany and help the researcher during the record examinations for the data collection. Blood lead level results were located in the record and recorded in a coded database; following this process all identifiable information linking the child's name to the collected data in the database was destroyed.

Data Analysis

Data collected was coded and entered into a database created using the Statistical Package for the Social Sciences (SPSS). Table 3 presents the research purposes, research questions, the variables measured, and the statistical analyses initially proposed. Additional analyses were made as needed during the data analysis process and are discussed in Chapter Four.

Statistical analyses were selected considering the scales of the independent and dependent variables. Since the variables involved in the study were both categorical (high or low SES, pre-natal alcohol exposure, birth weight, gestational age) and numeric (lead exposure, SMD), analyses performed were appropriate for both types of variables.

First Research Aim

The first aim of this research study was to examine the prevalence of SMD in PR preschoolers from high and low SES. Descriptive statistics were used to determine the prevalence of SMD. Following guidelines suggested by McIntosh et al. (1999), total scores of the SSP were used to identify children with SMD. McIntosh et al. (1999) found that total scores in the definite difference range indicate that the child does not process sensory information in a way that facilitates an adequate interaction with the environment. Children are identified as being in the definite difference range if they score two standard deviations or more below the mean, indicating performance commensurate with the lowest two percent of the normative sample. For descriptive purposes, children with such scores in this study were considered as having SMD.

In addition, a two-way Analysis of Variance (ANOVA) was used to determine

Table 3

Research Questions, Variables and Statistical Analyses

Specific aims	Research questions	Variables	Statistical analyses
1. To establish the presence and examine the prevalence of SMD in a sample of PR preschoolers from different SES.	1.1 What is the overall prevalence of SMD in a sample of Puerto Rican preschoolers? 1.2. Does the presence of SMD differ among preschoolers from diverse SES?	 IV- household income, and higher educational degree reached by caregiver(s) DV- SMD- was measured using total scores from the Spanish Short Sensory Profile (SSP, Dunn, 1999)	- Descriptive statistics to examine prevalence of SMD - Two way ANOVA to evaluate if sensory modulation abilities are different among preschoolers having diverse characteristics associated to SES
*2. To determine if relationships between sensory modulation and the identified risk factors could be explained by an exploratory path analysis model	2.1/3.1. Is the estimated population covariance matrix generated by the model consistent with the sample covariance matrix of the data for sampled preschoolers? 2.2/3.2. How much of the variance in SMD is accounted for by the risk factors? (i.e., What's the relative importance of each risk factor in the model?)	IV- Risk factors DV- SMD (total scores of the SSP)	- Structural Equation Modeling (SEM) Path Analysis
3. To explore changes in the relationships between sensory modulation and the identified risk factors when the variable lead exposure is included as an additional risk factor in a second exploratory path analysis model for a part of the sample	2.3/3.3. Within the model, what is the relative importance of the different paths?	IV- Risk factors DV- SMD (total scores of the SSP)	- Structural Equation Modeling (SEM) Path Analysis

IV- Independent variable; DV- Dependent variable

* Research questions, variables, and statistical analyses are the same for specific aims two and three.

whether prevalence of SMD among preschoolers differed in terms of their SES.

According to Tabachnick, and Fidell (2007), Factorial ANOVA can be used to determine differences in one continuous variable in terms of multiple discrete independent variables. In this case, the continuous dependent variable was represented by total scores on the SSP, while the discrete independent variables were the highest educational level reached by caregiver(s) of the child, and household income. Since two independent variables were involved in this study, a two way ANOVA was performed. SPSS was used to complete this statistical analysis.

Second and Third Research Aims

The second aim of this study was to determine if relationships between sensory modulation and the identified risk factors could be explained by an exploratory path analysis model based on findings of prior studies. The third aim was to explore changes in the relationships between sensory modulation and identified risk factors when the variable, lead exposure, is included as an additional risk factor in a second exploratory path analysis model for a part of the sample. Structural Equation Modeling (SEM) – Path Analysis was used to answer questions related to these aims. SEM consists of a set of statistical techniques (Path Analysis among them) that allow examination of relationships between one or more independent variables, either continuous or discrete, and one or more dependent variables, either continuous or discrete (Tabachnick & Fidell, 2007). In addition, unlike other strategies for analysis, SEM provides a means of controlling for extraneous or confounding variables as well as measurement error (Hoyle, 1995). Thus, it was considered appropriate for use in this study.

SEM requires formal specification of a model to be estimated and tested. That model must be based on literature. Figures 11 and 15 in Chapter Four present the proposed path analysis diagrams of the models that were evaluated in this study. The model in Figure 11 was used for the whole sample, while the model in Figure 15 was used only with the participants from Head Start (for whom data about the variable lead exposure was collected).

Preparation of the Database

A series of steps were followed in preparation for the data analysis. These entailed decisions from dealing with missing data to procedures to verify compliance with assumptions necessary for the analyses performed. All preparations are presented in the following paragraphs.

Missing Data

The database was revised to identify subjects with missing data. The only variable with missing values was the blood lead levels of the Head Start children. Of the 78 participants from Head Start, 29 (37%) did not have results of blood lead tests registered in the record reviewed at the Head Start districts. Coordinators of the districts indicated that there was a high quantity of children that did not have the information in their profiles because many parents still failed to have these tests performed on their children, even though they were oriented about the importance of the test.

There are no firm guidelines available about how much missing data can be tolerated for a sample of a given size (Tabachnick & Fidell, 2007). As a general rule, Tabachnick and Fidell (2007) indicate that if 5% or less of the missing data of a large

database is missing at random, it is possible that results are the same, regardless of inclusion or exclusion of the cases with missing values. However, results might be different if the database is small, as was the sample size of this study.

It is recommended to verify if data is missing at random, prior to making decisions about estimation of the missing data. A t-test was made using the presence/absence of missing values as the independent variable and the results of the Short Sensory Profile (SSP) as the dependent variable. Results indicated that there was no significant difference in the results of the SSP between the subjects with and without missing values in the blood lead level variable ($t = -1.746$; $df = 76$; $p = .085$). Since it was not possible to identify any pattern of missing data, it was concluded that data was missing at random.

Considering that missing values were scattered through only one variable (blood lead levels) and understanding the relevance of that variable for the study, as well as the significant loss of subjects that deletion of cases with missing values would entail, it was decided to choose an estimation (imputation) technique. Many critiques have been made about the use of single imputation methods such as arithmetic mean imputation and regression imputation. According to Enders (2010), despite the convenience of their use to produce complete data sets, these techniques do not entail compelling advantages because they distort the resulting parameter estimates.

On the other hand, Maximum Likelihood estimation techniques are regarded as state-of-the-art missing data techniques because they yield unbiased parameter estimates

under a missing-at-random mechanism (Schafer & Graham, 2002; Enders, 2010). The SPSS Missing Value Analysis (MVA) with Maximum Likelihood Expectation Maximization (EM) method was used to estimate the missing values. The system works by forming a missing data correlation matrix that assumes the shape of the distribution of the partially missing data and bases inferences about missing values on the likelihood under that distribution (Tabachnick & Fidell, 2007). EM is an iterative procedure of two steps. First, the E step (expectation) finds the conditional expectation of the missing data, given the observed values and current estimates of parameters. Then, the M step updates estimates of the mean vector and the covariance matrix. After convergence is achieved, the EM variance – covariance matrix is provided (Enders, 2010; Tabachnick & Fidell, 2007), which allowed the SPSS MVA to generate a data set with imputed values for the blood lead level variable. Despite its various advantages, inferences based on analysis using this and other imputation techniques should be made with caution because they do not add error to the imputed data set (Tabachnick & Fidell, 2007).

Outliers

An outlier is a case with such an extreme value on one variable that it distorts statistics (Tabachnick & Fidell, 2007). To determine the presence of outliers in the dependent variable, standardized residuals were examined using the Weisberg statistic (Stevens, 2002), which allows researchers to determine if a residual separates significantly from the others. The formula for the Weisberg statistic is:

$$t_i = \sqrt{(n - k' - 1 / n - k' - r_i^2)}$$

where n = sample size

k' = quantity of predictors, including the regression constant (weeks of pregnancy, birth weight, education, income, and the constant- plus lead in the case of the Head Start sample)

r_i = standardized residual

It should be noted that the variables “alcohol consumption” and “smoking” were eliminated from the statistical analyses performed because, as will be discussed, they did not comply with assumptions required for the analyses, such as normality and collinearity. They therefore did not count as predictor variables when calculating the Weisberg statistic. The following results were obtained:

- Weisberg statistic for the whole sample (n = 141):
 - o The t calculated using the Weisberg formula was .8390. The critical value for n = 141 and k' = 5 was 3.61.
 - o The value obtained was lower than the critical value. Thus, no outliers were identified in the criterion.
- Weisberg statistic for the Head Start sample (n = 78):
 - o The t calculated using the Weisberg formula was .8370. The critical value for n = 78 and k' = 6 was 3.55.
 - o The value obtained was lower than the critical value. Thus, no outliers were identified in the criterion.

To evaluate the presence of multivariate outliers among the predictors, Mahalanobis distance was calculated using SPSS. Mahalanobis distance is the distance of a case from the point created at the intersection of the means of all variables (Tabachnick & Fidell, 2007). Relevant results of this analysis are presented next.

- Mahalanobis distance for the whole sample ($n = 141$)
 - The critical value for $\alpha = .05$; $n = 141$, $k = 4$ is 18.43 (Stevens, 2002).
 - Mahalanobis distance for case # 125 = 42.30. This was the only case of the sample identified as an outlier.
- Mahalanobis distance for the Head Start sample ($n = 78$)
 - The critical value for $\alpha = .05$; $n = 78$, $k = 5$ is 20.26 (Stevens, 2002)
 - Two cases were identified as outliers
 - Case # 169- Mahalanobis distance = 21.68
 - Case # 14- Mahalanobis distance = 25.53

Once outliers were identified, it was necessary to determine if they were influential cases or not (Tabachnick & Fidell, 2007). Influential cases have an impact in the determination of the regression equation. As suggested by Tabachnick and Fidell (2007), Cook distance was used to identify influential cases. It measures the change that would occur in the coefficients of the equation if the influential case were omitted. According to Stevens (2002), a Cook distance greater than one indicates that if the influential case was eliminated, the equation would change significantly. None of the Cook distances calculated with SPSS were greater than one (neither for the whole sample

nor the Head Start sample). Thus, none of the outliers were influential cases and they were kept as part of the database.

Assumptions

Multivariate statistical analyses, such as the ones needed in this study, require the verification of a myriad of assumptions, which are discussed next.

Normality.


Skewness and kurtosis coefficients were calculated using SPSS to determine if the variables had a normal distribution. Skewness assesses deviations from the symmetry of the distribution while kurtosis looks at extremes in the peakedness of a distribution. Table four shows the coefficients for each of the variables for the whole sample and for the Head Start sample.

To determine if skewness and kurtosis coefficients deviate significantly from zero (normality), Tabachnick and Fidell (2007) suggest the use of an alpha of 0.01 and a critical z value of ± 2.57 . All values in Table 4 exceed the critical value except for the kurtosis coefficients of the variables SSP and education, and the skewness coefficient for the variable income in the whole sample. Exceptions in the Head Start sample were the kurtosis coefficient of the variable income and the skewness and kurtosis coefficients of the variables education and SSP (which means they were the only ones with a normal distribution). Based on the coefficient values, it is possible to presume that alcohol consumption and smoking are the variables with the greater deviations from the normal distribution.

Distribution of variables was also examined through the use of histograms (see

Table 4

Skewness and Kurtosis Coefficients

Variables	Total sample (n = 141)		Head Start sample (n = 78)	
	Skewness	Kurtosis	Skewness	Kurtosis
Education	-3.23	-2.17	.38	-2.03
Household income	2.50	-2.81	5.81	2.91
Birth weight	-18.37	36.16	-13.21	25.16
Weeks of pregnancy	-11.06	7.14	-8.34	5.99
Alcohol consumption	-18.18	35.11	-22.50	67.64
Smoking	-58.21	347.29	-32.46	144.98
SSP results	-3.16	1.80	-2.33	1.07
lead			9.76	35.01

Note. The space corresponding to the variable lead under the total sample column has been blocked out because data about lead was collected only for the Head Start sample.

Figure 6). This confirmed results obtained with the analysis of skewness and kurtosis coefficients. The histograms presented in Figure 6 allow comparison between the distribution of the variables education and SSP for the Head Start sample (which were identified as having normal distributions), and the variables alcohol consumption and smoking (which had the greater deviations from a normal distribution).

Multivariate normality.

Given the lack of univariate normality, it is possible to assume noncompliance with the assumption of multivariate normality. This was confirmed through examination of standardized residuals (i.e., the differences between the predicted and the obtained values of the dependent variable). Figure 7 shows the P-Plots of the standardized residuals for the complete sample and for the Head Start sample.

Residual points in both plots show discrepancy from the superimposed straight line, which indicates data deviates from multivariate normality. This was expected, in part due to the categorical nature of some of the variables in this study, which was a

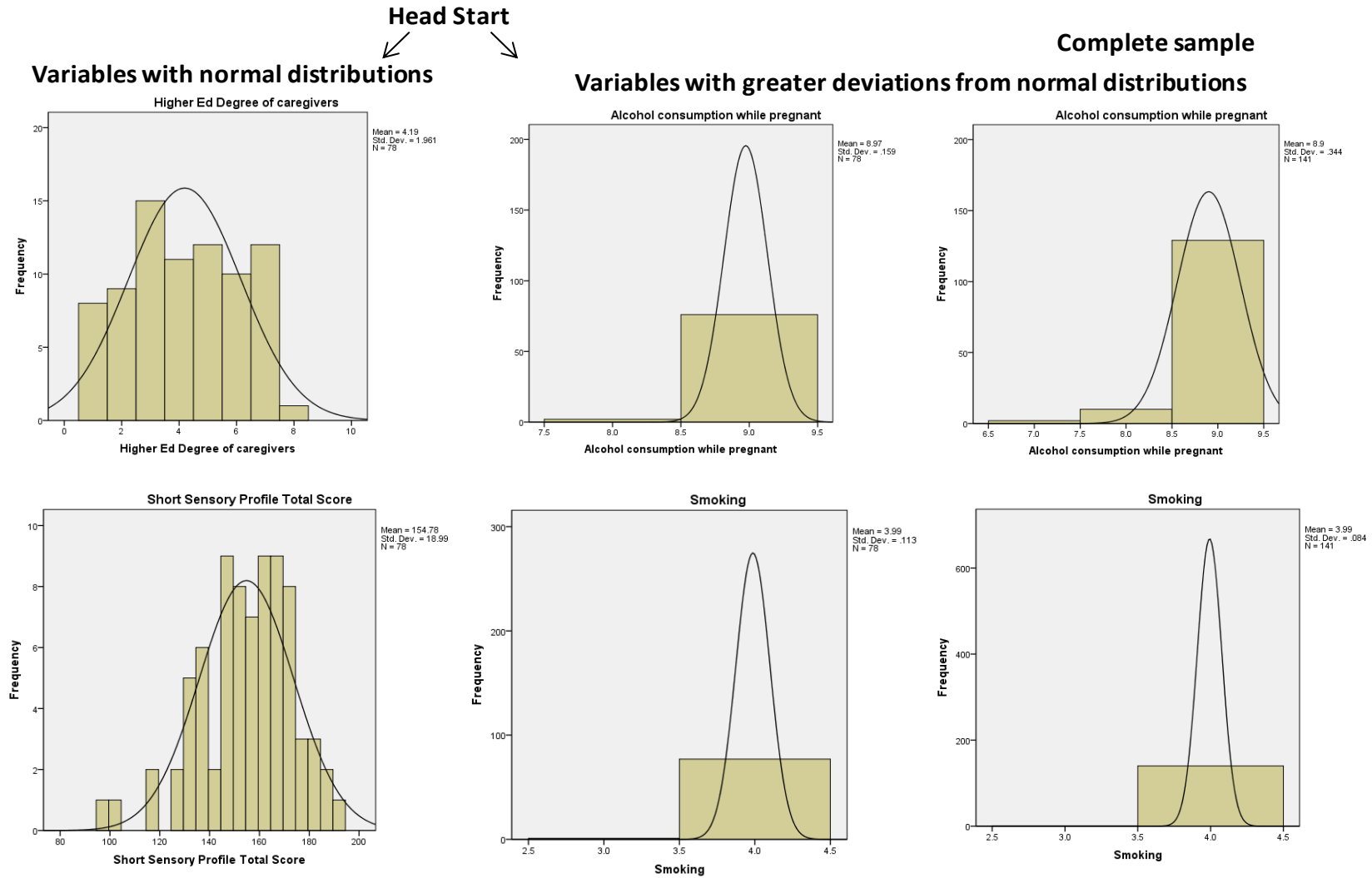


Figure 6. Selected Histograms of Variables with Normal and Non-Normal Distributions.

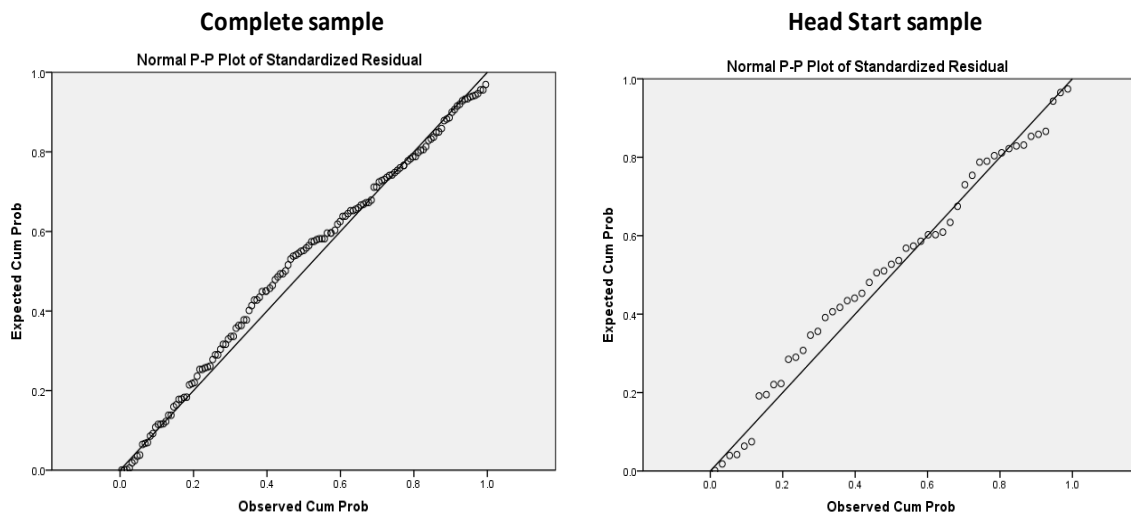


Figure 7. P-Plots of Standardized Residuals to Assess Multivariate Normality.

limitation considered during the performance of statistical analyses, as will be seen in Chapter Four.

Collinearity.

Collinearity occurs when variables are too highly correlated. To verify collinearity issues among the variables in the study, the condition index was calculated using SPSS. Table 5 presents the condition indexes related to each variable in the study for the whole sample and for the Head Start sample. Condition indexes also allow the analysis of differences between indexes obtained when the variables “alcohol consumption” and “smoking” are considered and when they are eliminated from the analysis.

Condition indexes higher than 30 are indicative of collinearity (Tabachnick & Fidell, 2007). Indexes for the variables alcohol consumption and smoking are all greater than 30. In addition, it was observed that, in general, condition indexes of the other

Table 5

Collinearity Diagnostics for the Complete Sample and the Head Start Sample

Variables	Complete sample		Head Start sample	
	CI (including variables 5 and 6)	CI (not including variables 5 and 6)	CI (including variables 5 and 6)	CI (not including variables 5 and 6)
1. Education	4.31	3.85	5.14	4.53
2. Income	11.62	9.75	7.13	6.34
3. Birth weight	17.35	18.23	18.59	20.22
4. Weeks of pregnancy	35.11	32.45	32.83	30.58
5. Alcohol consumption	81.39	---	114.55	---
6. Smoking	185.43	---	237.33	---
7. Lead			8.58	7.44

Note. CI= Condition index. Space corresponding to the lead variable under the total sample column was blocked out because data about lead was collected only for the Head Start sample.

variables improved when these variables were not included in the analysis. On the other hand, the condition index of the variable *weeks of pregnancy* was slightly higher than 30. According to Tabachnick and Fidell (2007), if the index is greater than 30, but the variance proportion is lower than .50, it can still be considered that there is no collinearity.

In the complete sample, the variance proportion of the variable weeks of pregnancy was .46 (when alcohol consumption and smoking were included), and .26 (when alcohol consumption and smoking were not included). In the case of the Head Start sample, the variance proportion of weeks of pregnancy was .47 (when alcohol consumption and smoking were included), and .22 (when alcohol consumption and smoking were not included). Thus, weeks of pregnancy was considered as a variable with no collinearity issues and was included as part of the statistical analyses. On the other hand, due to the marked collinearity issues and deviations from normality, alcohol

consumption and smoking were not included as part of the statistical analyses of this study, as discussed in Chapter Four.

Linearity.

Scatterplots of residuals vs. predicted values were made to determine if independent variables (risk factors) correlated linearly with the dependent variable. Tabachnick and Fidell (2007) establish that in plots showing linearity, residuals are equally distributed above and below the horizontal zero line, and on both sides of the vertical zero line. As shown in Figure 8, the distribution of residuals improved when the variables alcohol consumption and smoking were eliminated from the linearity analysis.

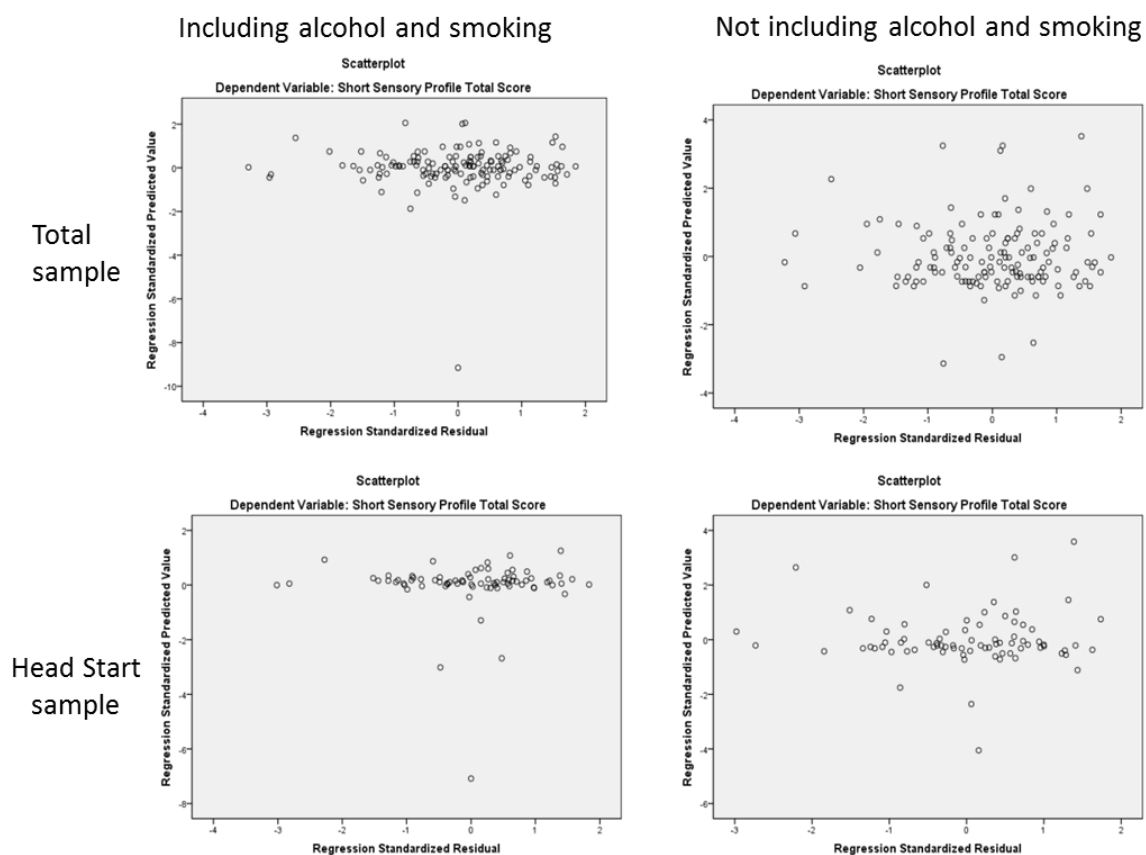


Figure 8. Selected Scatterplots of Standardized Residuals to Assess Linearity.

Residuals of the scatterplots at the right of the figure (those not including the variables alcohol consumption and smoking) are better distributed than residuals of the scatterplots at the left (those including the variables alcohol consumption and smoking). Scatterplots not including the variables alcohol and smoking, indicate that the linearity assumption is met in the total sample, but not in the Head Start sample. This could be explained by the skew inherent to the variable household income in the Head Start sample (who as expected, reported lower incomes), and to the inclusion in the analysis of the variable lead exposure, an additional variable (not considered for the total sample) with a non-normal distribution. Figure 9 allows comparison between the total sample and the Head Start sample of the bivariate scatterplot to assess the linear relationship between household income and scores in the SSP. Figure 10 presents the bivariate scatterplot of the variables lead exposure and scores in the SSP.

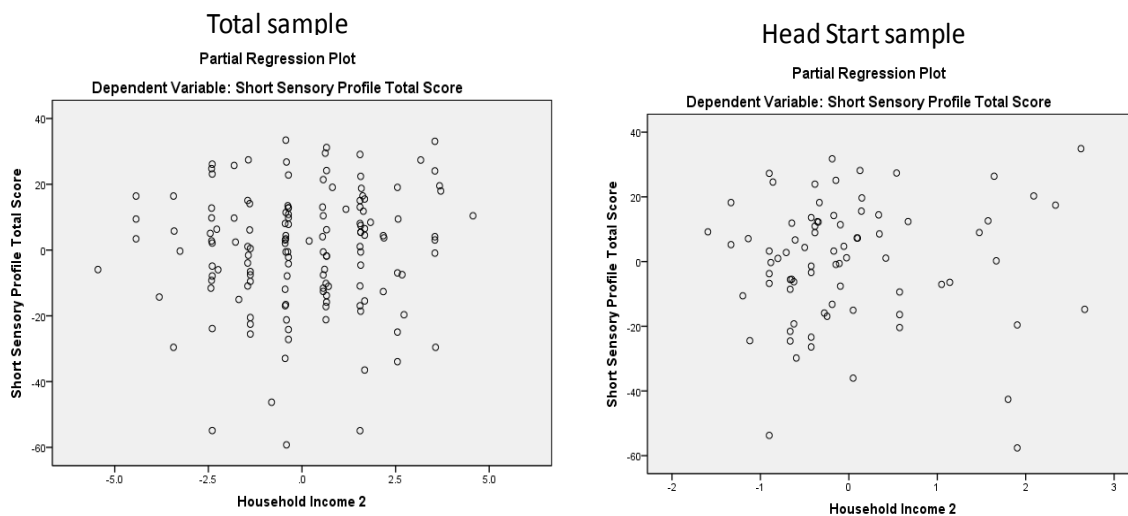


Figure 9. Scatterplots to Assess Linearity of the Relationship Between Household Income and Scores in the SSP.

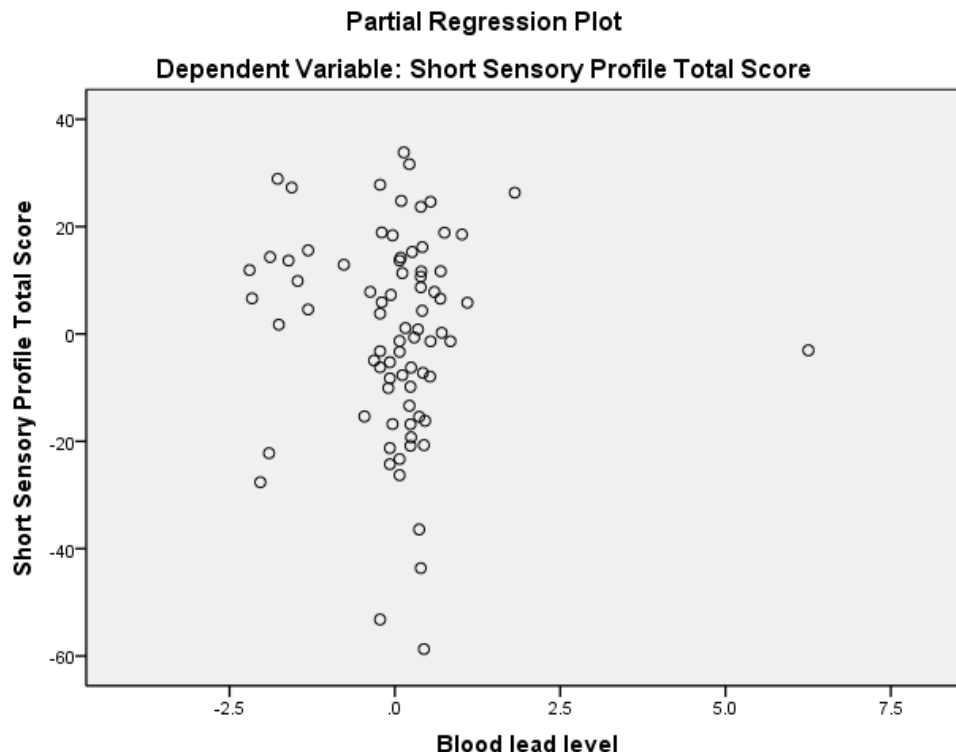


Figure 10. Scatterplot to Assess Linearity of the Relationship Between Lead Exposure and Scores in the SSP (Head Start Sample).

As shown in Figure 9, linearity of the variable household income was better in the total sample than in the Head Start sample. Figure 10 shows that the variable lead exposure, measured by blood lead levels, did not show a linear relationship with the variable SSP. This lack of linear relationship implies a limitation because some statistical techniques might ignore non-linear relationships between variables. This is part of the reason why (as will be discussed in Chapter Four) it was necessary to perform additional analyses not based on the assumption of linearity (e.g., SEM with Bayesian estimation).

Summary of the Process of Preparation of the Database

Points presented below summarize the results of the preparation of the database:

1. Missing values were observed only for the variable lead exposure. After verifying that values were missed at random, Enders' (2010) recommendation of using Missing value analysis with Expectation Maximization was followed. For this purpose, the SPSS Missing value analysis tool was used. The procedure generated a data set with imputed values for those cases where the blood lead level data was missed (thus providing a complete data set).
2. No univariate outliers were identified. Only one multivariate outlier was identified in the total sample; and two in the Head Start sample. None of these outliers resulted in an influential case. Thus, they were kept as part of the statistical analyses.
3. Only two variables complied with the assumption of normality: education and SSP for the Head Start sample. In general, the variables education, household income, and SSP showed approximately normal distributions. Alcohol consumption and smoking were the variables with the greater deviations from normality. P-Plots of standardized residuals showed an approximately multivariate normal distribution for the total sample, but not for the Head Start sample. These were considered as limitations inherent to the categorical nature of some variables (i.e., all variables except SSP results and lead were categorical). In the case of the Head Start sample, the results were also due to its characteristics (e.g., they had lower incomes, which inherently entails a distribution deviated from normality).
4. All variables, except alcohol consumption and smoking, complied with the collinearity assumption (see Table 5). Some issues were observed with the variable

weeks of pregnancy; however, the variable was kept as part of the risk factor dataset (see the previous section entitled “Collinearity”).

5. Scatterplots of standardized residuals for the total sample showed an approximate linear relationship among variables for the total sample, but not for the Head Start sample.

After these analyses, it was decided to eliminate the variables alcohol consumption and smoking from the rest of the statistical analyses, because of their marked lack of compliance with assumptions such as normality and collinearity. As expected, it was hard to achieve compliance with statistical assumptions, given the use of categorical variables (Portney & Watkins, 2008). However, aspects such as the presence of values missed randomly for only one variable (which made possible the performance of the methodological procedure of MVA), the absence of influential outliers, the normal distribution of the dependent variable, the approximate normal distribution for some of the independent variables, as well as variables that showed compliance with the collinearity assumption and an approximate linear relationship among the variables were strengths of the database. These strengths made it possible to carry out the proposed statistical analysis. On the other hand, recognizing the limitations related to the lack of compliance with some of the assumptions, more flexible analyses that consider the categorical nature of the variables were also performed to: (1) validate and complement results of the analyses initially proposed; and (2) assess if relationships among variables supported those indicated in the literature. Results of the study corresponding to the proposed analyses are described in Chapter Four.

CHAPTER IV

Results

Sample Characteristics

A total of 141 caregivers participated in this study. Seventy eight were from Head Start programs: 48 from Head Starts located at the municipalities of Toa Baja and Cataño and 30 from Vieques. Sixty-three participants were parents from private preschools located at Guaynabo. All subjects met the inclusion criteria. Four cases were excluded only for purposes of statistical analyses related to research questions 2.1 to 3.3 (concerning the relationship between the identified risk factors and the prevalence of SMD, see Table 3 in Chapter Three). Two of these cases were children whose caregivers indicated they had a pervasive developmental disorder and two were of caregivers of children with ADHD.

The mean age of children sampled was 48 months. Of the 141 children, 68 were female and 73 were male. Table 6 summarizes additional information about the participants and specifies characteristics of children from private preschools and Head Start programs.

Most children in the total sample lived with both parents ($n = 94$). The majority of private school preschoolers lived with both parents (92.1%) as did nearly half of the Head Start preschoolers (46.2%). However, a high percentage of Head Start children lived with

Table 6

Characteristics of the Sample

Descriptive variables	Total sample <i>n</i> =141		Private preschools <i>n</i> =63		Head Starts <i>n</i> =78	
	Frequency (<i>f</i>)	Percentage (%)	Frequency (<i>f</i>)	Percentage (%)	Frequency (<i>f</i>)	Percentage (%)
Gender						
- Females	68	48.2	26	41.3	42	53.8
- Males	73	51.8	37	58.7	36	46.2
Person with whom the child lives						
- Mother and father	94	66.7	58	92.1	36	46.2
- Mother only	19	13.5	2	3.2	17	21.8
- Grandparents	4	2.8	1	1.6	3	3.8
- One parent and one grandparent	12	8.5	0	0	12	15.4
- Other	12	8.5	2	3.2	10	12.8
Educational degree						
- 8 th grade or less	8	5.7	0	0	8	10.3
- 9 th -12 th	9	6.4	0	0	9	11.5
- Graduated from high school or equivalent	15	10.6	0	0	15	19.2
- Some college courses	12	8.5	1	1.6	11	14.1
- Certificate	13	9.2	1	1.6	12	15.4
- Associated degree	11	7.8	1	1.6	10	12.8
- Bachelor's degree	37	26.2	25	39.7	12	15.4
- Graduated degree	36	25.5	35	55.6	1	1.3
Household income						
- Less than \$10,000	49	34.8	0	0	49	62.8

Table 6. Continued

Descriptive variables	Total sample <i>n</i> =141		Private preschools <i>n</i> =63		Head Starts <i>n</i> =78	
	Frequency (<i>f</i>)	Percentage (%)	Frequency (<i>f</i>)	Percentage (%)	Frequency (<i>f</i>)	Percentage (%)
- \$10,000-14,999	15	10.6	0	0	15	19.2
- \$15,000-24,999	9	6.4	3	4.8	6	7.7
- \$25,000-34,999	9	6.4	3	4.8	6	7.7
- \$35,000-49,999	10	7.1	8	12.7	2	2.6
- \$50,000-74,999	13	9.2	13	20.6	0	0
- \$75,000-99,999	11	7.8	11	17.5	0	0
- \$100,000-149,999	12	8.5	12	19.0	0	0
- \$150,000-199,999	6	4.3	6	9.5	0	0
- More than \$200,000	7	5.0	7	11.1	0	0
Birth weight						
- 3.3 pounds or less	1	.7	0	0	1	1.3
- 3.4- 5.5 pounds	10	7.1	4	6.3	6	7.7
- 5.6 pounds or more	130	92.2	59	93.7	71	91.0
Weeks of pregnancy						
- 36 weeks or less	18	12.8	8	12.7	10	12.8
- 37 weeks or more	123	87.2	55	87.3	68	87.2
Alcohol consumption						
- ...	0	0	0	0	0	0
- Once a month	2	1.4	2	3.2	0	0
- A few scattered occasions	10	7.1	8	12.7	2	2.6

Table 6. Continued

Descriptive variables	Total sample <i>n</i> =141		Private preschools <i>n</i> =63		Head Starts <i>n</i> =78	
	Frequency (<i>f</i>)	Percentage (%)	Frequency (<i>f</i>)	Percentage (%)	Frequency (<i>f</i>)	Percentage (%)
- Never	129	91.5	53	84.1	76	97.4
Smoking						
- ...	0	0	0	0	0	0
- Half a pack or less	1	.7	0	0	1	1.3
- None	140	99.3	0	0	77	98.7
Child's condition						
- PDD	2	1.4	2	3.2	0	0
- ADD or ADHD	2	1.4	0	0	2	2.6
- Down Syndrome	1	.7	0	0	1	1.3
- Other	26	18.4	8	12.7	18	23.1
- None	110	78.0	53	84.1	57	73.1

Note. PDD = Pervasive Developmental Disorder; ADD = Attention Deficit Disorder; ADHD = Attention Deficit Hyperactivity Disorder.

their mother only or with one parent and one grandparent (a total of 37% vs. 3.2% in the case of preschoolers from private schools). Table 6 also displays comparisons according to educational degree and household income of the caregivers of children. As expected, participants from private preschools had higher educational degrees and household incomes than participants from Head Start centers, which is consistent with the Head Start mission of serving families from low socioeconomic status (SES) households.

The percentage of low birth weight children was slightly higher among Head Start children (9% vs. 6.3% at private school). The number of children born prematurely was

similar at Head Start and private preschools (12.7% at private preschools and 12.8% at Head Starts).

Information provided by caregivers about alcohol consumption and smoking during pregnancy must be examined carefully. The great majority of the total sample indicated they never displayed these behaviors during pregnancy ($n = 129$ for alcohol consumption, and $n = 140$ for pregnancy smoking). Only one participant from Head Start reported smoking during pregnancy, a total of one to 10 cigarettes daily, which was the lowest category of smoking frequency indicated in the questionnaire. Of the 12 participants that indicated alcohol consumption, 10 were from private preschools.

Two children of participants from private preschools had been diagnosed with Pervasive Developmental Disorder (PDD), and two children from Head Start participants had Attention Deficit Disorder (ADD) or Attention Deficit Hyperactivity Disorder (ADHD). As noted earlier, these cases were excluded from the analysis. There was one child with Down Syndrome and a total of 26 children with other conditions included in the sample (most of them with language delay, as specified by their caregivers). The child with Down Syndrome was included in the sample because he did not meet specific diagnostic exclusion criteria and did not present with significant motor impairments.

Finally, descriptive information about the variable lead exposure does not appear in Table 6 because it was a continuous variable. Children's values of blood lead levels ranged from .3 to 9.3 $\mu\text{g/dL}$, with a mean value of 2.67 $\mu\text{g/dL}$. None of the values exceeded the limit established by the CDC (2005) of 10 $\mu\text{g/dL}$ which is considered a high blood lead level for a child. However, there is evidence that children with blood lead

levels as low as 2µg/dL can suffer from cognitive and behavioral deficits (Gilbert & Weiss, 2008; Landrigan, Schechter, Lipton, Fahs, & Schwartz, 2002). Thus only for purposes of a subsequent MANOVA analysis, where lead exposure needed to be re-coded to a categorical variable to be used as an independent variable, blood lead levels equal or lower than 2µg/dL were labeled as low levels (n= 14), while values higher than 2µg/dL were labeled as high (n= 62).

Results Related to the First Research Aim (Research Questions 1.1 and 1.2- See Table 3)

The first research aim of this study was to examine the prevalence of SMD in a sample of PR preschoolers. Descriptive statistics indicated that the prevalence of SMD in the total sample was 19.9% (n = 28). This number reflects the percentage of subjects under the definite difference category on the SSP. Subjects who fell under the probably different category equaled 21.3%, while 58.9% were classified under the typical performance category. Table 7 presents the results of the total sample in the seven domains of the SSP.

The SSP domains with the higher percentage of participants under the definite difference classification were Underresponsive/seek sensation, followed by tactile sensitivity and auditory filtering (38.3%, 17.0%, and 15.6%, respectively). As expected, the higher frequency of children were grouped under typical performance for all the domains, except for the Underresponsive/ seeks sensation domain. For this section, the frequency of children under the definite difference category (n= 54) was nearly equivalent to the frequency of children presenting a typical performance (n= 53).

Table 7

Results of the Total Sample in the Domains of the SSP (n = 141)

Domains	Typical performance		Probable difference		Definite difference	
	n	%	n	%	n	%
Tactile sensitivity	97	68.8	20	14.2	24	17.0
Taste/smell sensitivity	107	75.9	16	11.4	18	12.8
Movement sensitivity	108	76.6	19	13.5	14	9.9
Underresponsive/ seeks sensation	53	37.4	34	24.1	54	38.3
Auditory filtering	93	65.9	26	18.5	22	15.6
Low energy/weak	114	80.9	8	5.7	19	13.5
Visual/auditory sensitivity	93	65.9	28	19.8	20	14.2
Total	83	58.9	30	21.3	28	19.9

It was hypothesized that sensory modulation abilities (as indicated by higher scores on the SSP) would be greater among preschoolers whose caregivers had higher educational degrees and higher household incomes. A two way ANOVA was performed to examine differences in SSP scores using the higher educational degree reached by caregivers and the household income as independent variables. First, homogeneity of variance was verified using the Levene's test, and the results supported homogeneity ($F = 1.48, p = 0.065$). Since no significant difference was found between the variances of the independent variables, it was possible to proceed with the ANOVA test. Results are presented in Table 8.

Table 8

Results of the Analysis of Variance

Source of variance	<i>df</i>	Mean squared	<i>F</i>	Partial Eta Squared	<i>p</i>
Household Income	9	321.384	.934	.075	.499
Educational degree	7	184.020	.535	.035	.806
Income*Education	20	303.388	.882	.145	.610
error	104	344.079			

All the *p* values in the table exceed the established alpha of .05. Results do not support the hypothesis. There was no significant difference in scores on the SSP based on preschoolers' SES.

Results Related to the Second and Third Research Aim (Research Questions 2.1-3.3- See Table 3)

The second aim of this study was to determine if relationships between sensory modulation and the identified risk factors could be explained by an exploratory path analysis model. The third research aim was to explore changes in those relationships when the variable lead exposure was included as an additional risk factor in a second exploratory path analysis model.

Structural Equation Modeling for the Total Sample (Research Questions 2.1-2.3)

Structural equation modeling using maximum likelihood estimation was the technique used to address the second and third research aims. The model initially

proposed to explore relationships between risk factors and SMD is presented in Figure 11.

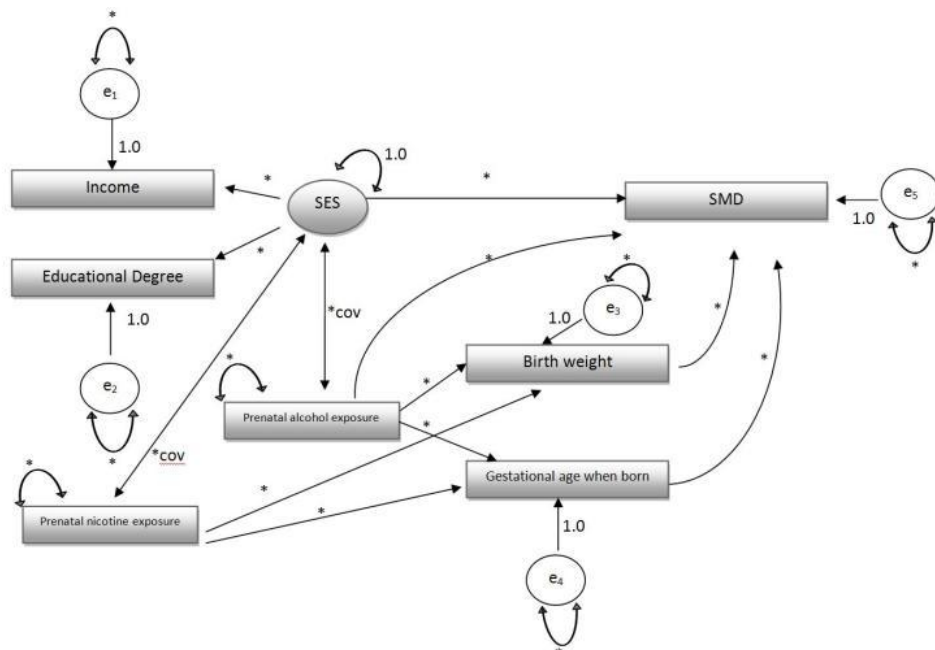


Figure 11. Path Diagram of the Model Proposed for the Whole Sample.

One of the main purposes of SEM is to find the model that provides the best explanation about the relationship between the independent and dependent variable in the model; in this case those variables were the risk factors and sensory modulation (measured by SSP total scores). Research question 2.1 asked whether the estimated population covariance matrix generated by the model was consistent with the sample covariance matrix of the data. In SEM, models are analyzed and re-specified as needed in order to achieve the most succinct model or, as described by Schumacker & Lomax (2004), in order to determine the number of estimated parameters required to achieve a specific level of fit (i.e., the principle of parsimony).

Amos SPSS was used to examine all the models analyzed in this study. The use of the model in Figure 11 was not possible since, as explained, the variables alcohol consumption and smoking were eliminated from the statistical analyses due to their lack of compliance with statistical assumptions (see section “Preparation of the data base” in Chapter Three). Thus, the first model analyzed had two latent variables: SES, formed by education and income; and birth, comprised of birth weight and weeks of pregnancy (see Figure 12). Results of the analysis indicated that the solution was not admissible because the error variance of the variables weeks of pregnancy and income were negative and this affected the positive definition of the covariance matrix. A possible reason for this was the use of a small sample size along with the inclusion of latent variables in the model, which increases the number of parameters to be estimated (Kline, 2011).

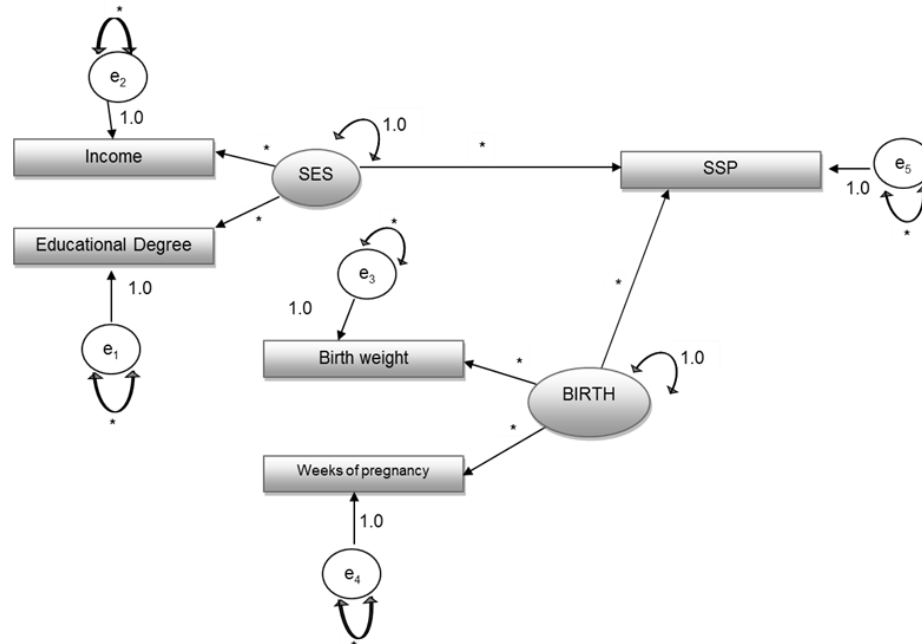


Figure 12. Model with Two Latent Variables Analyzed for the Total Sample.

A re-specification was made and a second model with no latent variables was tested (see Figure 13). The solution was admissible. However, results ($X^2 = 69.54$; $df = 5$; $p = 0.00$) indicated a poor fit of the model. A good fit is indicated by a non-significant X^2 , defined by a p greater than .05, which was not the case here. Additionally, the Normed Fit Index (NFI) was revised. The NFI is a measure that rescales chi-square into a 0 (no fit) to 1.0 (perfect fit) range (Schumacker & Lomax, 2004). Values close to or higher than .95 reflect a good model fit. The NFI for the model in Figure 13 was .63, confirming the poor fit showed by the X^2 . As discussed in the section “Preparation of the data base” in Chapter Three, the condition index of the variable weeks of pregnancy (see Table 5) showed some collinearity issues (though its variance proportion was lower than 0.50). This was probably due to the relationship with the variable birth weight.

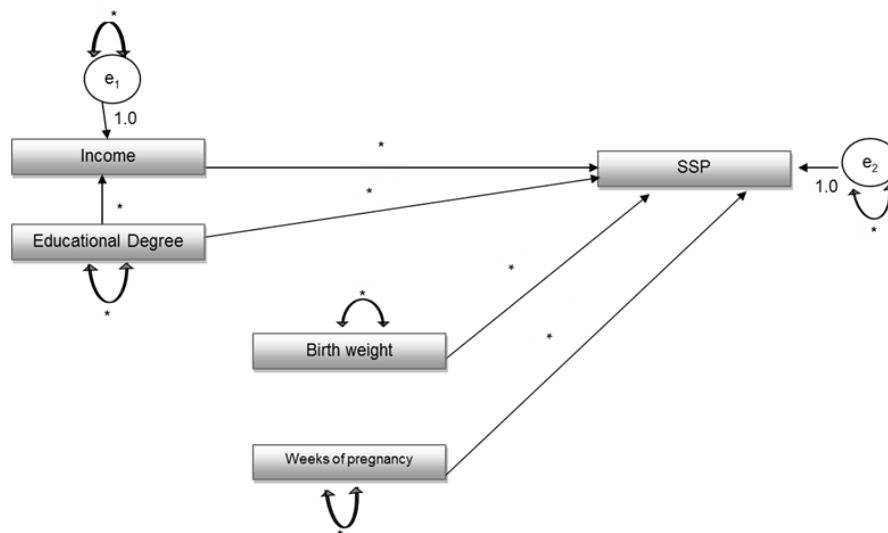


Figure 13. Model with No Latent Variables Analyzed for the Total Sample.

A third model was tested eliminating the variable weeks of pregnancy (see Figure 14). The solution was admissible and the X^2 showed no significance ($X^2 = 1.82$; $df = 2$; $p = 0.40$). The NFI was 0.98. To confirm the finding of a parsimonious solution, the Akaike Information Criterion (AIC) was revised. Small values of the AIC indicate a good fit (Tabachnick & Fidell, 2007). No specific rules have been established about how small the AIC index should be. Tabachnick and Fidell (2007, p. 719) indicate that “small enough is small as compared to other competing models.” The AIC index for this model was 17.82 while the AIC for the model in Figure 13 was 89.54. Findings to answer research question 2.1 indicate a good fit between the covariance matrix generated by the model and the covariance matrix of the sample. This suggests that the model is good to explain the relationship between the included risk factors and score on the SSP, based on the observed data.

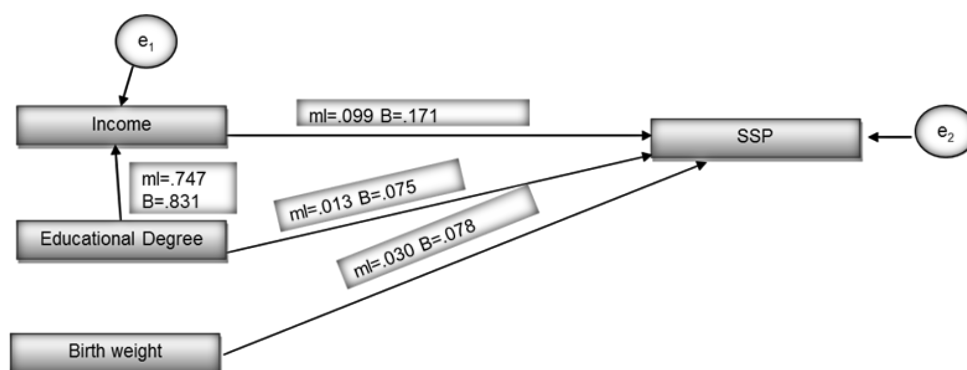


Figure 14. Final Model Analyzed for the Total Sample.

Note. ml = regression weight calculated with Maximum Likelihood estimation; B = regression weights calculated with Bayesian estimation.

Squared multiple correlations were used to answer research question 2.2, which asked about the variance in SSP scores accounted for by the risk factors. It was estimated

that only a 0.9% of the variance in total SSP scores was explained by the risk factors included in the model. In other words, the error variance of SSP was approximately 99.1%. This implies that, in spite of the good fit obtained with the model, additional factors need to be considered to understand factors underlying sensory modulation abilities.

SEM Using Bayesian Estimation for the Total Sample

Once the most parsimonious solution was found, the model in Figure 14 was assessed using a methodological approach for analysis of categorical data provided by SPSS Amos. This is based on Bayesian estimation. Bayesian statistics are a set of methods for the orderly expression and revision of belief as new data evidence is gathered (Kline, 2005). Under the Bayesian approach parameters are treated as random variables having a probability distribution rather than as fixed (but unknown) numbers. Statistical inference relies on the posterior distribution of a parameter, given the data (Agresti, 2010).

The Bayesian estimation process does not assess the model fit by using a classic p-value to assess significance. Instead, it uses a posterior predictive p-value to see if the value of an observed test statistic is extreme relative to the posterior distribution of the statistic. Thus, large values (close to one) or small values (close to zero) indicate a lack of plausibility for the model (Congdon, 2006). The posterior predicted p-value obtained for the model assessed was .50, which indicates good model plausibility (Convergence statistic- CS = 1.016; 30,001 samples were generated). The convergence statistic criterion established was 1.10, as suggested by Gelman, Carlin, Stern, and Rubin (2004). The CS

indicates the point at which enough samples have been drawn to generate stable parameter estimates.

Standardized regression weights were verified to answer research question 2.3 about the relative importance of the different paths in the model. The low percentage of variance in SMD accounted for by the risk factors, allows anticipation of low regression weights. Table 9 shows the standardized regression weights obtained with the Maximum likelihood (ML) estimation and with the Bayesian approach.

Table 9

Standardized Regression Weights for the Total Sample

Parameter	Estimation approach	
	ML	Bayesian
Education > Income	.747	.831
Education > SSP	-.013	-.075
Income > SSP	.099	.171
Birth weight > SSP	.030	.078

Regression weights also appear in the model of Figure 14. For both estimation approaches, the risk factor with the relative greater weight was income, followed by birth weight, and education. However, under the Bayesian approach, birth weight and education showed basically the same relative importance explaining the prevalence of SMD. As anticipated, all direct effect values were low.

Structural Equation Modeling for the Head Start Sample (Research Questions 3.1-3.3)

An additional model was proposed to explore changes in the relationships between risk factors and sensory modulation when the variable lead exposure was included as part of the analysis. This was done using data from subjects from Head Start preschools (since results of blood lead tests were available only for this part of the sample). The model proposed is showed in Figure 15.

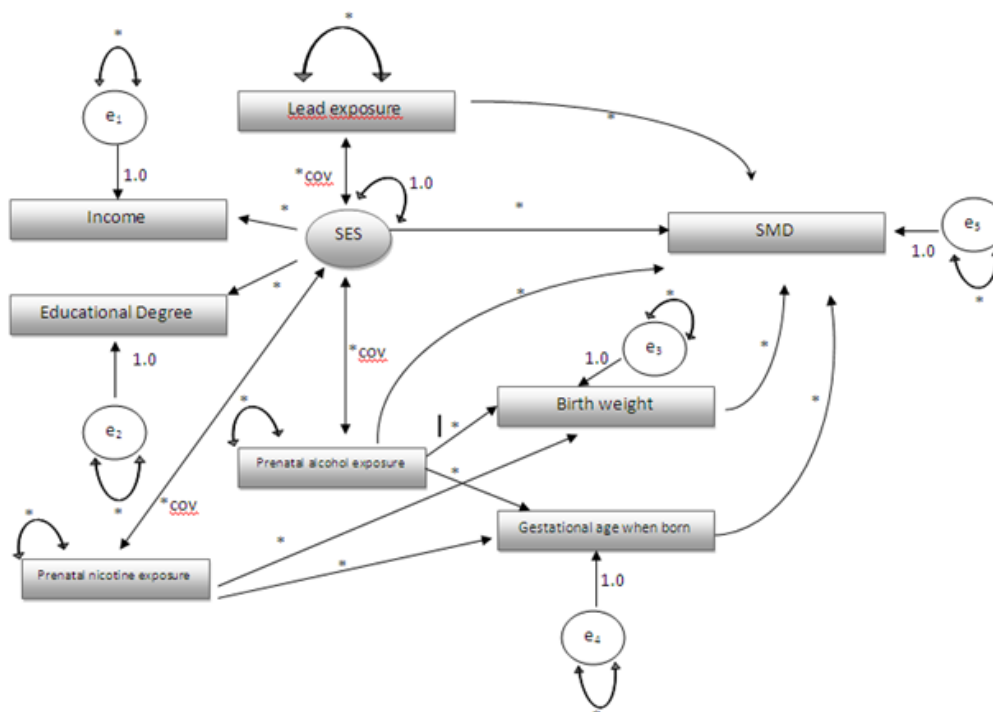


Figure 15. Path Diagram of the Model Proposed for the Head Start Sample

A process similar to the one followed with the total sample was made in order to achieve the goal of SEM which was to get a parsimonious model with a few substantive meaningful paths and a non-significant chi-square value (Schumacker & Lomax, 2004). As was the case for the proposed model for the total sample, it was not possible to analyze the proposed model for the Head Start sample because of the inclusion of the

variables alcohol consumption and smoking. The first model analyzed was the same as the model shown in Figure 12. The only difference was it also included blood lead level as a dependent variable. The solution of this model was not admissible.

As with the total sample, a second model with no latent variables was tested for the Head Start sample (see Figure 16). The solution was admissible, but results indicated a poor fit of the model ($X^2 = 42.09$; $df = 9$; $p = 0.00$). The Normed Fit Index value was much lower than .95, thus confirming the poor fit of the model to the data (NFI = 0.255).

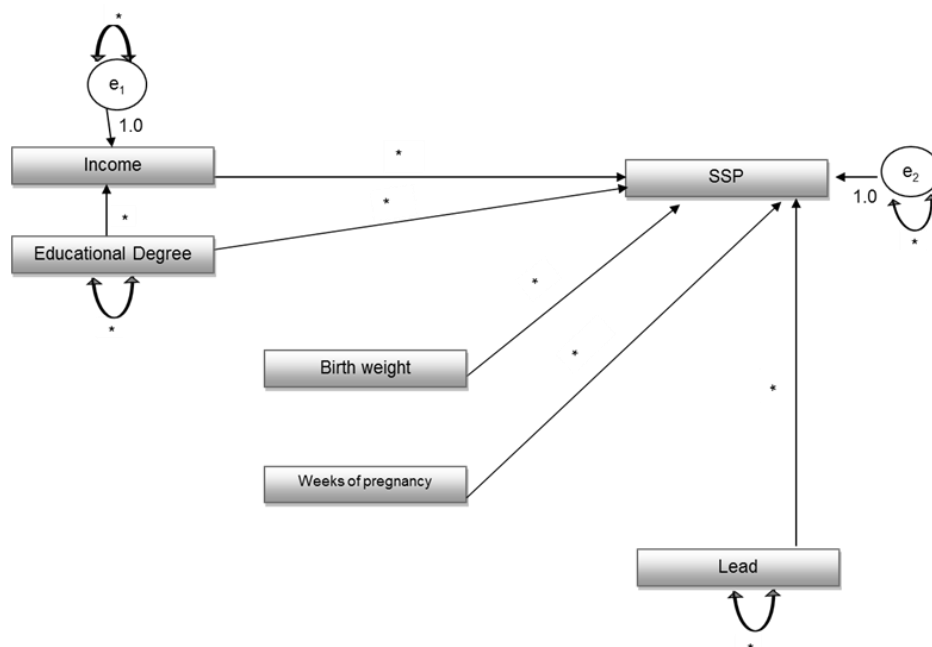


Figure 16. Model with No Latent Variables Analyzed for the Head Start Sample.

A third model was tested, eliminating the variable weeks of pregnancy because of suspected collinearity issues. This model is presented in Figure 17. It is similar to the one in Figure 14 for the total sample.

With this model, the solution was admissible with a chi-square showing no significance ($X^2 = 6.15$; $df = 5$; $p = 0.29$). Verification of the NFI (NFI = 0.70) showed an

adequate fit of the model. Although the model of Figure 14 for the total sample showed a better fit ($NFI = 0.98$), the AIC of this model (Figure 17) showed the most parsimonious solution among the models tested for the Head Start sample ($AIC = 26.15$ vs. AIC of the model in Figure 16 = 66.09). As an answer to research question 3.1, findings indicate that, based on the observed data, the model offers an adequate explanation for the relationships between the risk factors and sensory modulation.

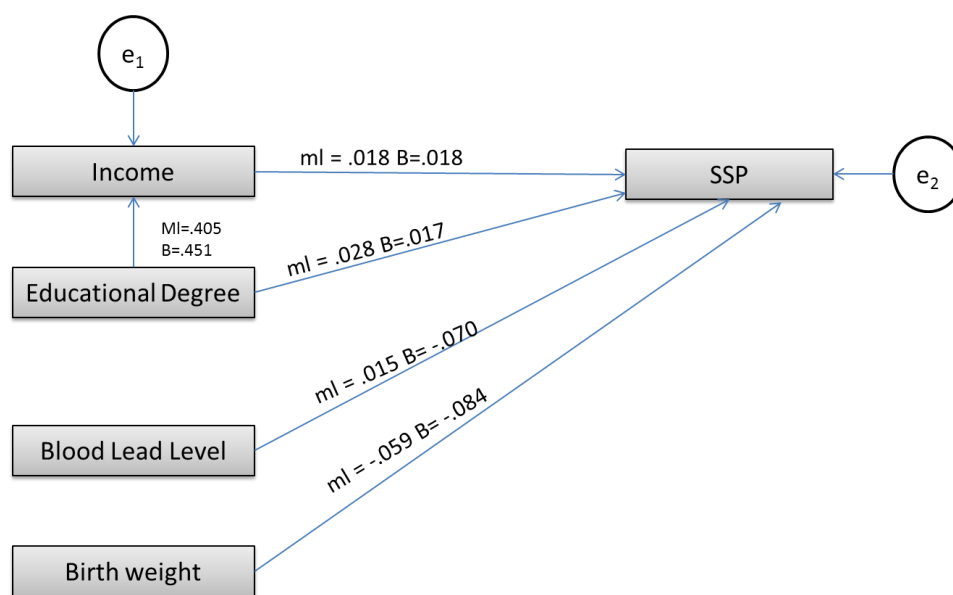


Figure 17. Final Model Analyzed for the Head Start Sample.

Note. ml = regression weight calculated with Maximum Likelihood estimation; B = regression weights calculated with Bayesian estimation.

Research question 3.2 (variance in SMD accounted for by the risk factors) was answered through examination of squared multiple correlations. Only 0.5% of the variance in SSP scores was explained by the risk factors included in the model. Thus, the error variance of SSP was approximately 99.5%. As observed with the total sample, even though an adequate fit was obtained, additional factors must be considered to explain total scores on the SSP.

SEM Using Bayesian Estimation for the Head Start Sample

The model with the most parsimonious solution (Figure 17) was assessed using Bayesian estimation, an approach to analysis of categorical data. The posterior predictive p-value obtained for the model was 0.39 (CS = 1.019; 49,385 samples were generated). Results indicated adequate model plausibility.

Standardized regression weights were verified to determine the relative importance of the different paths in the model (research question 3.3). As expected, based on the low percentage of variance in SMD accounted for by the risk factors, regression weights were low. Table 10 includes regression weights obtained with the ML and the Bayesian estimation approaches.

Table 10

Standardized Regression Weights for the Head Start Sample

Parameter	Estimation approach	
	ML	Bayesian
Education > Income	.405	.451
Education > SSP	.028	.017
Income > SSP	.018	.018
Birth weight > SSP	.015	-.070
Lead > SSP	-.059	-.084

The risk factor with the relative greater weight was lead, using both estimation approaches. In the ML approach, lead was followed by education, income, and birth weight as variables with the highest regression weights. In the Bayesian approach, birth weight got the second place of relative importance, followed by income, and education.

Nonetheless, the values are very low. Indeed, it is not possible to assert with certainty a real difference between the regression weights of income and birth weight in the ML estimation, nor between education and income or birth weight and lead in the Bayesian approach. Therefore, additional analyses were performed to further examine the relationship between the risk factors and sensory modulation.

Cluster Analysis for the Total Sample

Cluster analysis is a group of multivariate techniques intended to assemble objects based on the characteristics that they possess (Hair & Black, 2006). It can be used with nominal, ordinal, and ratio variables. Although cluster analysis has been traditionally related to objects/subjects grouping, in this study it was applied as an exploratory technique to determine which risk factors (if any) grouped along with SSP (Hair & Black, 2006). Such a grouping would be considered as a reason to go in depth with additional analyses to identify the most relevant risk factors.

The analysis was performed in SPSS. Two groups resulted. The variables education and income grouped as did the variables birth weight, weeks of pregnancy, and SSP. The resultant proximity matrix is presented in Table 11.

Values in Table 11 are Euclidean distances. They indicate proximity between each pair of variables. A hierarchical agglomerative procedure was used to form the clusters (Hair & Black, 2006). At the beginning of this process, each variable forms its own cluster. Then, the two closest variables, not already in the same cluster (Euclidean distance between birth weight and weeks of pregnancy = 2.722), are identified. Afterward, the closer variable to either of the previously identified variables is also

Table 11

Proximity Matrix of the Cluster Analysis for the Total Sample

	Education	Income	Birth weight	Weeks of pregnancy	SSP
Education	.00				
Income	19.091	.00			
Birth weight	21.446	59.139	.00		
Weeks of pregnancy	23.641	57.250	2.722	.00	
SSP	13.707	38.160	5.742	7.255	.00

identified and combined with that cluster (distance between SSP and birth weight = 5.74).

The process is repeated until all of the variables are in a single cluster (agglomerative).

Figure 18 shows a dendrogram, which depicts a representation of the clustering process and the clusters formed.

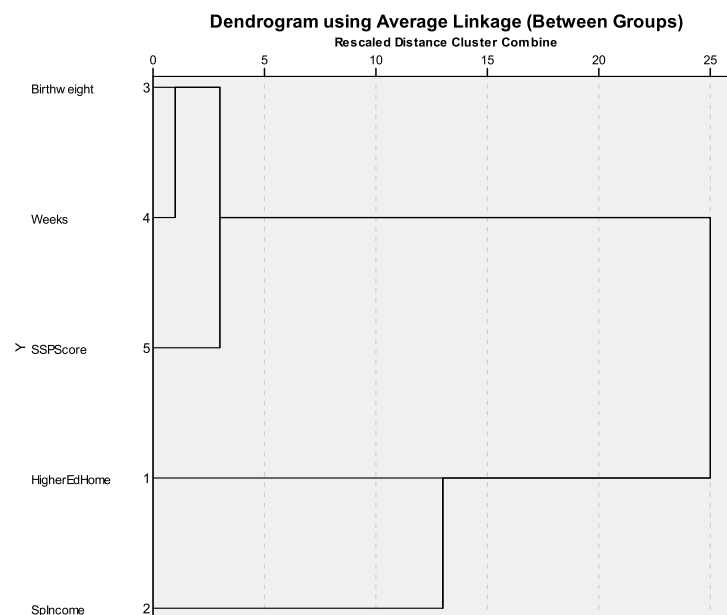


Figure 18. Clustering Dendrogram for the Total Sample.

The horizontal axis of the dendrogram indicates the distance between the clusters. As shown in Figure 18, birth weight and weeks of pregnancy formed the first cluster; then SSP became part of their cluster. Education and income formed a cluster. Later, both clusters were grouped together. The two cluster solution is indicated by the significant change in the distance between the cluster formed by birth weight, weeks of pregnancy, and SSP, and the cluster formed by education and income.

Cluster Analysis for the Head Start Sample

Two groups also resulted from the cluster analysis of the Head Start sample. One included the variables education, income, and lead exposure; while the other included birth weight, weeks of pregnancy, and SSP. The proximity matrix is presented in Table 12.

Table 12

Proximity Matrix of the Cluster Analysis for the Head Start Sample

	Education	Income	Birth weight	Weeks of pregnancy	Lead exposure	SSP
Education	.00					
Income	7.657	.00				
Birth weight	20.325	35.071	.00			
Weeks of pregnancy	21.172	33.860	1.611	.00		
Lead exposure	9.545	5.083	38.901	37.011	.00	
SSP	11.884	22.091	3.532	4.191	24.279	.00

As with the total sample, a hierarchical agglomerative clustering procedure was used. Based on Euclidean distances in the proximity matrix, the first cluster was formed by the variables birth weight and weeks of pregnancy (Euclidean distance = 1.611). Just like in the total sample, SSP became part of that cluster (Euclidean distance between SSP and birth weight = 3.532). The whole clustering process is presented in Figure 19.

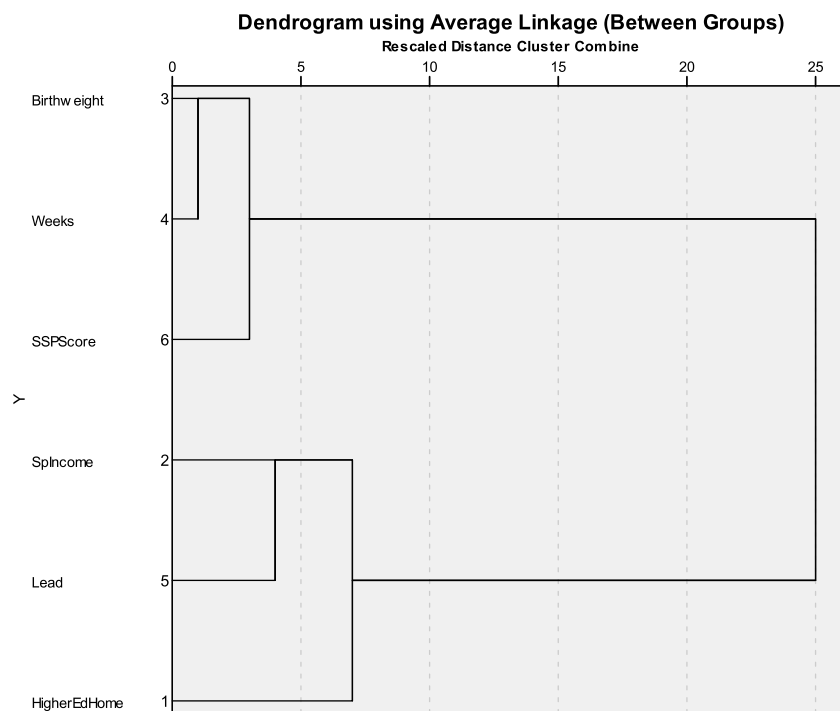


Figure 19. Clustering Dendrogram for the Head Start Sample

As shown in the dendrogram, the next cluster was formed by income and lead. Then, education became part of that cluster. The two cluster solution is indicated by the significant change in the distance between the cluster formed by birth weight, weeks of pregnancy, and SSP, and the one formed by income, lead, and education.

The fact that the variable SSP did group with other variables (birth weight and weeks of pregnancy) suggest that it was worth performing additional analyses to identify

the most relevant risk factors among those included in the study and to assess whether the proximity (grouping) of these variables is due to a relationship between them, as the literature suggests.

Sections of the SSP Used as Dependent Variables in Analyses of Variances: Total Sample

The Short Sensory Profile (SSP) has seven sections that are scored separately. The total score is calculated from the sum of the sections' scores. All analyses discussed to this point have used the total score of the SSP as the dependent variable.

Seven one way analyses of variances were performed using the risk factors as independent variables and each of the sections of the SSP as dependent variables. Table 13 shows the results of those ANOVA. Significant p-values were those lower than .05. Some of the lowest p-values obtained are also included in the table because, although they did not reach the significant level ($p < 0.05$), they allowed further examination of variables identified as relevant in the literature. Only significant p-values appear in bold.

As presented in Table 13, participants' whose caregivers had different educational degrees differed in scores on the movement sensitivity section of the questionnaire ($F = 2.346$; $df = 7$; $p = 0.027$). Post hoc tests using Tukey HSD indicated that differences were found between educational degrees of eighth grade or less and those who held a bachelor's degree (mean difference = -2.25 ; $p = 0.05$).

Scores on the Underresponsive/seek sensation section were also different based on the educational degree reached by caregivers ($F = 2.088$; $df = 7$; $p = 0.049$). The lowest p-value was found among individuals with some college courses and those with a graduate degree (mean difference = -6.06 ; $p = 0.078$). For scores in the section

Table 13

ANOVA for the Sections of the SSP (Total Sample)

	<i>df</i>	SS	MS	<i>F</i>	<i>p</i>	R squared
Dependent variable: Movement sensitivity						
Education	7	57.537	8.220	2.346	.027	.113
Error	129	451.909	3.503			
Total	137	25762.000				
Dependent variable: Underresponsive/seeks sensation						
Education	7	525.562	75.080	2.088	.049	.102
Error	129	4638.074	35.954			
Total	137	91691.000				
Income	9	593.203	65.911	1.832	.069	.115
Error	127	4570.432	35.988			
Total	137	91691.000				
Birth weight	2	192.321	96.160	2.592	.079	.037
Error	134	4971.314	37.099			
Total	137	91691.000				
Dependent variable: Tactile sensitivity						
Birth weight	2	96.908	48.454	3.472	.034	.049
Error	134	1870.202	13.957			
Total	137	130175.000				

Note. SS = Sum of squares; MS = Mean square. Significant p-values appear in bold.

Underresponsive/seeks sensation, lowest p-values were observed for the variables income ($F = 1.832$; $df = 9$; $p = 0.069$) and birth weight ($F = 2.592$; $df = 2$; $p = 0.079$). The greatest difference for the variable income was observed between participants whose household income was less than \$10,000 and participants who earn more than \$200,000 annually (mean difference = -7.33; $p = 0.140$). Post hoc tests were not performed with the variable birth weight because the first level of that variable (3.3 pound or less) had only one case. Birth weight did present as a significant variable to explain differences in scores on the Tactile Sensitivity section of the SSP ($F = 3.472$; $df = 2$; $p = 0.034$).

Sections of the SSP Used as Dependent Variables in Analyses of Variances: Head Start Sample

Based on the results of the ANOVA made for the Head Start sample, it was not possible to identify significant differences in scores on any of the sections of the SSP for any risk factor. P-values nearest to .05 are included in Table 14.

Table 14

ANOVA for the Sections of the SSP (Head Start Sample)

	<i>df</i>	<i>SS</i>	<i>MS</i>	<i>F</i>	<i>p</i>	<i>R squared</i>
Dependent variable: Auditory Filtering						
Income	4	140.624	35.156	2.209	.077	.111
Error	71	1130.113	15.917			
Total	76	44092.000				
Dependent variable: Tactile sensitivity						
Birth weight	2	92.239	46.119	2.989	.057	.076
Error	73	1126.551	15.432			
Total	76	72162.000				

Note. SS = Sum of squares; MS = Mean square.

P- values of the variables income and birth weight were near to .05 in reference to scores on the sections auditory filtering and tactile sensitivity (see Table 14). Post hoc Tukey HSD tests indicated greater difference in scores on the Auditory filtering section was observed between participants with household incomes of less than 10,000, and those with incomes of \$15,000-24,999 (mean difference = 3.94; $p = 0.164$). Additionally, birth weight was linked with differences in the Tactile Sensitivity section, but no post hoc test was made because the first level of that variable (3.3 pounds or less) had only one case.

It was not possible to perform an ANOVA for the variable lead exposure because of its nature as a numerical variable. Significant or near to significant differences in scores on some sections of the SSP were related to some of the risk factors. Therefore, the last steps taken to examine the data included exploratory factor analysis with sections of the SSP used to create new factors (composed by combination of sections of the SSP) in order to reduce the number of dependent variables. This allowed performance of Multivariate Analysis of Variance (MANOVA) reducing type I error.

Factor Analysis with Sections of the SSP (Total Sample)

Factor analysis is a statistical technique applied by researchers for the purpose of discovering which variables in a set form coherent subsets that are relatively independent from one another. Variables correlated with one another but largely independent from other subsets of variables are combined into factors (Tabachnik & Fidell, 2007).

Alpha factoring extraction with varimax rotation was performed with the sections of the SSP using SPSS dimension reduction. Alpha factoring is an extraction method that uses Cronbach's alpha to obtain a measure of internal consistency of the extracted factors

(Pett, Lackey & Sullivan, 2003). It is the most appropriate method in cases where the focus is on drawing general conclusions about the structure of a domain (in this case, SMD, as defined by the results of the SSP) (Tinsley & Tinsley, 1987). Varimax is an orthogonal rotation procedure in which the goal is to simplify factors by maximizing the variance of the loadings within factors, across variables. It is the most commonly used rotation (Tabachnick & Fidell, 2007). Varimax was selected over other rotation methods because the rationale of the analysis was to maximize variance between the resulting factors (Tabachnick & Fidell, 2007). This implies that the factors resulting from the analysis were as independent as possible from each other (i.e., not correlated). As opposed to the varimax method, the use of other methods such as an oblique rotation does not require the rotation process to keep the factors uncorrelated (Meyers, Gamst, & Guarino, 2006). This was not in accordance to the purpose of the analysis since the intention was to observe if the sections of the SSP grouped in two or more *independent* factors that could be used as dependent variables in subsequent analysis.

Two factors were extracted. Table 15 shows the results obtained including factor loadings, eigenvalues, and percentage of variance related to each factor.

Sections with factor loadings of .32 or higher were retained for analysis (Tabachnick & Fidell, 2007). The factor loading of the section movement sensitivity for the first factor was .360. However, its loading for the second factor was .439. Thus it was kept under factor two. This factor solution explained 39.50% of the variance.

Sections grouped in the first factor were Tactile sensitivity, Underresponsive/seeks sensation, Auditory filtering, and Taste/smell sensitivity; while

Table 15

Results of the Factor Analysis with Sections of the SSP for the Total Sample

Sections of the SSP	Factor I Seeks as a regulatory mechanism	Factor II Passive response as a regulatory mechanism
Tactile sensitivity	.691	
Underresponsive/seeks sensation	.574	
Auditory filtering	.494	
Taste/smell sensitivity	.375	
Low energy/weak		.673
Visual/auditory sensitivity		.493
Movement sensitivity		.439
Eigenvalue	2.927	1.031
Percentage of variance	20.227	19.27
Cumulative percentage	20.227	39.497

sections grouped in the second factor were Low energy/weak, Visual/auditory sensitivity, and Movement sensitivity. Each item of the SSP was analyzed in terms of the sensation and the threshold to which it was related. To this purpose, the complete Sensory Profile (from which items of the SSP are taken) was used as reference. All items of sections under factor one were predominantly related with a low threshold, except for the Underresponsive/seeks sensation section. On the other hand, all items of sections under factor two were predominately related to a low threshold, except for those of the Low

energy/weak section. Thus, there were no definite patterns of high or low threshold among the items that composed the sections forming the two factors.

It was decided to focus attention on the higher factor loadings (Factor I: .69 for Tactile sensitivity; .57 for Underresponsive/seeking sensation; Factor II: .67 for Low energy/weak). This suggested that Factor one might represent children who were easily distracted or disturbed by daily tactile, auditory or taste/smell stimuli and tended to use *sensation seeking* as a regulatory mechanism (label given to the first factor). Conversely, children easily disturbed by common visual/auditory and movement stimuli may be predisposed to use a *passive response* (indicated by the section low energy/weak) as a regulatory mechanism (label given to the second factor).

Factor Analysis with Sections of the SSP (Head Start Sample)

Alpha factoring extraction with varimax rotation was also used to perform factor analysis for the Head Start sample. As with the total sample, two factors were extracted. They were labeled the same as the factors obtained with the total sample, although their composition was slightly different when compared with those of the total sample. Results are presented in Table 16.

The factor solution explained 43.81% of the variance. With the Head Start sample, sections grouped under the first factor were: Low energy/weak, Visual/auditory sensitivity, and Auditory filtering. Sections grouped under the second factor were: Tactile sensitivity, Taste/smell sensitivity, Underresponsive/seeking sensation, and Movement sensitivity. Composition of factors was similar to those found in the total sample except for the interchanged factoring of the sections Auditory filtering and Movement sensitivity

Table 16

Results of the Factor Analysis with Sections of the SSP for the Head Start Sample

Sections of the SSP	Factor I Passive response as a regulatory mechanism	Factor II Seeking as a regulatory mechanism
Low energy/weak	.709	
Visual/auditory sensitivity	.653	
Auditory filtering	.492	
Tactile sensitivity		.629
Taste/smell sensitivity		.495
Underresponsive/seeks sensation		.491
Movement sensitivity		.490
Eigenvalue	3.179	1.041
Percentage of variance	24.986	18.823
Cumulative percentage	24.986	43.809

(see Table 17). Low energy/weak was the section with the highest factor loading (.709). All factor loadings of sections in the second factor were approximately .49 except for Tactile sensitivity (.629). As with the total sample, it was not possible to identify a definite pattern of high or low threshold factors.

Resultant factors for the Head Start sample were labeled the same as those of the total sample. Factor one was labeled as seeking as a regulatory mechanism; and factor two, passive response as a regulatory mechanism. It was understood that it is possible

Table 17

Factors Formed with the Total Sample and the Head Start Sample

	Factor I	Factor II
Total sample	<ul style="list-style-type: none"> - Tactile sensitivity - Underresponsive/seeking sensation - Auditory filtering - Taste/smell sensitivity 	<ul style="list-style-type: none"> - Low energy/weak - Visual/auditory sensitivity - Movement sensitivity
Head Start sample	<ul style="list-style-type: none"> - Tactile sensitivity - Taste/smell sensitivity - Underresponsive/seeking sensation - Movement sensitivity 	<ul style="list-style-type: none"> - Low energy/weak - Visual/auditory sensitivity - Auditory filtering

Head Start children who are easily disturbed by common visual and auditory stimuli tend to use a passive response as a regulatory mechanism, while those easily disturbed by tactile, taste/smell, and movement sensitivity tend to turn to seeking as a regulatory strategy.

Using a regression method through SPSS dimension reduction, scores were assigned to the new variables formed by the factors obtained from the factor analysis. This allowed the completion of the last step of the analysis process.

MANOVA for the Total Sample

Multivariate Analysis of Variance (MANOVA) can be used to determine if the effect of one or more independent variables on a group of two or more dependent variables is statistically significant (Tabachnick & Fidell, 2007). A MANOVA was performed for the total sample using the factors *seeking as a regulatory mechanism* (SRM) and *passive response as a regulatory mechanism* (PRM) as dependent variables.

Tabachnick & Fidell (2007) point to the importance of complying with the homogeneity of the covariance matrix when a MANOVA is performed because robustness is affected when cell sizes are unequal, as was the case in this study. Homogeneity of covariances was assessed using SPSS M Box's Test. Initial results indicated lack of equality of covariance matrices across groups. Thus, categories of the variables education, and income were collapsed in an effort to equalize cell sizes. Old and new levels of the variables are displayed in Table 18.

Both variables (education and income) ended with four levels, which resulted in more similar cell' sizes than with the old levels. The hypothesis of homogeneity of the covariance matrix was tested again and retained (Box M= 48.585; $p= 0.074$).

The MANOVA was performed using SPSS generalized linear models. As done in the SEM analysis, the variable weeks of pregnancy was not included for two reasons: (1) it presented indicators of some collinearity issues (see section "Preparation of the data base" in Chapter Three), and (2) it was included as part of the ANOVA analyses discussed previously and did not show any significant differences for any of the sections of the questionnaire.

Table 18

Old and New Levels of the Variables Education and Income

Variables and their levels	Old levels	Cells' size	New levels	Cells' sizes
Income:				
Less than 10,000	1	48	1	48
10,000-14,999	2	15		
15,000-24,999	3	9	2	24
25,000-34,999	4	8		
35,000-49,999	5	10	3	30
50,000-74,999	6	12		
75,000-99,999	7	11		
100,000-149,999	8	12		
150,000-199,999	9	6	4	35
More than 200,000	10	6		
Education:				
Eight grade or less	1	8		
9th-12th	2	9	1	32
Graduated from high school or equivalent	3	15		
Some college courses	4	11	2	24
Certification	5	13		
Associated degree	6	10	3	47
Bachelor's degree	7	37		
Graduated degree	8	34	4	34

Risk factors included as independent variables for the MANOVA were birth weight, income, and education (the same as in the final model of SEM for the total sample). None of the Wilks' Lambda values obtained were significant. However, Table 19 presents the results for those variables that showed lower p-values. In addition, Table 20 shows the post-hoc ANOVAs that presented lower p-values. Correspondent Levene's

Test supported the hypothesis of homogeneity of variance needed for the ANOVA analyses (SRM: $F = 1.207$; $p = 0.264$; PRM: $F = 1.024$; $p = 0.439$).

Table 19

MANOVA Results for the Total Sample

	Wilks' Lambda	F	Hypothesis df	Error df	p	Partial Eta squared	Observed power
Birth weight	.955	1.35	4	232	.252	.023	.418
Education	.918	1.681	6	232	.127	.042	.634

Table 20

Post Hoc ANOVAs (Total Sample)

Source of variance	Dependent variable	df	Mean square	F	p	Partial eta squared	Observed power
Birth weight	SRM	2	1.671	2.599	.079	.043	.509
Education	SRM	3	1.338	2.081	.106	.051	.521
Education*Income	SRM	5	.922	1.434	.217	.058	.490

Note. SRM = Seeking as regulatory mechanism.

According to the results of the MANOVA, risk factors were not related to significant differences on SRM or PRM. Birth weight and education were the variables with lower, but non-significant, p -values. Birth weight accounted for 2.3% of the variance on the linear combination of SRM and PRM while education accounted for 4.2% of the variance. Differences on both variables impacted the SRM dependent variable more than the PRM. Partial eta squared attributes 4.3% of the variance on SRM

to birth weight, and a 5.1% to education. The linear combination of education and income presented one of the lowest p-values, and accounted for 5.8% of the variance on SRM. In general, although not significant, results point to the potential importance of the variables birth weight and education.

MANOVA for the Head Start Sample

A MANOVA similar to the one performed with the total sample was performed for the Head Start sample, except that lead was included as part of the independent variables. Procedures followed were similar to the ones explained previously. Levels of the variables income and education were collapsed and re-coded in order to achieve similar cells sizes. Re-code of the variable education, which was different from the one in the total sample, is presented in Table 21.

Table 21

Old and New Levels of the Variable Education

Variables and their levels	Old levels	Cells' size	New levels	Cells' sizes
Education:				
Eighth grade or less	1	8		
9th-12th	2	9	1	17
Graduated from high school or equivalent	3	15	2	15
Some college courses	4	10		
Certification	5	12	3	22
Associated degree	6	9		
Bachelor's degree	7	12	4	22
Graduated degree	8	1		

Additionally, a re-code was made to the variable blood lead level in order to make it a categorical variable as needed for the MANOVA. There is evidence to suggest that children with blood lead levels as low as 2µg/dL can suffer from cognitive and behavioral deficits (Gilbert & Weiss, 2008; Landrigan, Schechter, Lipton, Fahs, & Schwartz, 2002). Using this as a guideline, blood lead level (BLL) was re-coded into a categorical variable. BLL equal to or lower than two were labeled as low levels, while levels higher than two were labeled as high. There were 14 subjects with levels equal or lower than 2µg/dL, and 62 subjects with levels higher than 2 µg/dL.

Results of the M Box Test supported homogeneity of covariances (Box M = 54.913; $p= 0.063$). Risk factors included as independent variables were BBL, income, birth weight, and education. Dependent variables were seeking as a regulatory mechanism (SRM) and passive as a regulatory mechanism (PRM). Results of the MANOVA and post hoc ANOVAs related to variables with the lowest p-values are shown in Tables 22 and 23. Levene's Test supported the hypothesis of homogeneity of variance for the ANOVA analyses (PRM: $F = 1.28$; $p= 0.232$; SRM: $F= 1.363$; $p= 0.182$).

Results of the MANOVA indicate that risk factors were not related to significant differences on PRM. BLL and the linear combination of birth weight and education were the variables with the lowest p-values; however, none were significant. BLL accounted for 4.8% of the variance on the linear combination of PRM and SRM and birth weight*education accounted for 5.1% of the variance. Nonetheless, observed power coefficients are low, especially for BLL. Conversely to what was observed with the total

Table 22

MANOVA Results for the Head Start Sample

	Wilks' Lambda	<i>F</i>	Hypothesis df	Error df	<i>p</i>	Partial Eta squared	Observed power
Birth							
weight*Education	.898	1.497	4	108	.208	.051	.451
BLL	.952	1.354	2	54	.267	.048	.279

Table 23

Post Hoc ANOVAs (Total Sample)

Source of variance	Dependen t variable	df	Mean square	<i>F</i>	<i>p</i>	Partial eta squared	Observed power
BLL	PRM	1	1.471	2.757	.103	.048	.371
Birth weight*							
education	PRM	2	.829	1.553	.221	.053	.316

Note. PRM = passive response as regulatory mechanism.

sample, identified variables with lower p-values appear to impact the PRM dependent variable more than the SRM. Partial eta square attributed 4.8% of the variance on PRM to BLL and 5.3% to the linear combination between birth weight and education.

Nonetheless, ANOVA power coefficients are low, even lower than observed power of the correspondent analysis presented for the total sample. To conclude, although non-

significant, results point to the potential importance of the variables BLL, birth weight and education.

Summary of the Results Related to the Second and Third Research Aim (Research Questions 2.1-3.3)

Research question 2.1 asked if the estimated population covariance matrix generated by the path analysis model was consistent with the sample covariance matrix for sampled preschoolers. Research question 3.1 asked the same, but for the Head Start sample. The following points summarize results that answer those research questions:

1. Results based on the SEM analyses indicated a good fit between the covariance matrix generated by the model and the covariance matrix generated by the total sample ($X^2 = 1.82$; $df = 2$; $p = 0.40$; NFI = 0.98).
2. Fit was adequate in the case of the Head Start sample ($X^2 = 6.15$; $df = 5$; $p = 0.29$; NFI = 0.70).
3. Models were adequate to explain the relationships between the risk factors and the prevalence of SMD.

Research questions 2.2 and 3.2 were related to the quantity of variance in SMD accounted for by the risk factors for the total sample and for the Head Start sample. In spite of the fit that the models showed to the data, results of SEM indicated that in the total sample, only .9% of the variance in the scores of the SSP was explained by the risk factors. For the Head Start sample, .5% of the variance in SSP was explained by the risk factors.

Finally, research questions 2.3 and 3.3 asked about the relative importance of the variables for the total sample and the Head Start sample. Diverse steps were followed to answer these questions in order to consider the categorical nature of the variables:

1. Bayesian estimation was used along with Maximum Likelihood estimation to determine standardized regression weights in SEM. Tables 9 and 10 present results of both estimation techniques. For the total sample, income was the risk factor with the higher weight, followed by birth weight and education. For the Head Start sample, BLL had the higher weight, followed by education, income and birth weight. Using the Bayesian approach, birth weight took second place in the Head Start sample.
2. Given the low values of the regression weights and the low percentage of variance explained by the risk factors, additional analyses considering the categorical nature of the variables were performed. The first to be performed was a cluster analysis.
3. Two clusters formed for the total and the Head Start sample. In both cases, the variable SSP was grouped together with birth weight and weeks of pregnancy, while income and education formed their own cluster. In the case of the Head Start sample, lead became part of the cluster formed by income and education. The fact that SSP grouped with other variables led to the performance of additional analyses to examine if the proximity (groping) among variables was indicative of some relationships.
4. A series of ANOVAs were performed using sections of the SSP as dependent variables and risk factors as independent variables. For the total sample, the sections Movement sensitivity and Underresponsive/seeks sensation showed significant difference based on education; while Tactile sensitivity presented significant

difference based on birth weight. None of the ANOVAs were significant for the Head Start sample. However, lower p-values suggested possible differences on Auditory filtering based on education, and on Tactile sensitivity based on birth weight.

5. The next step was the determination of factors formed by sections of the SSP to be used as dependent variables in multivariate analyses of variances. Resultant factors were similar for the total and the Head Start sample (see Table 17). Indeed, they were labeled the same: Seeking as regulatory mechanism (SRM) and passive response as regulatory mechanism (PRM).
6. None of the MANOVAs using SRM and PRM as dependent variables resulted in significant effects. However, examination of lower p-values and post hoc ANOVAs pointed to the importance of birth weight and education for the total sample and BLL, birth weight, and education for the Head Start sample. This corresponds to the variables identified as relevant under the Bayesian approach of the SEM.

CHAPTER V

Discussion

This study was intended to characterize the relationship between identified risk factors and the prevalence of SMD among Puerto Rican preschoolers. The research aims specified were:

1. To establish the presence and examine the prevalence of SMD in a sample of PR preschoolers from different SES backgrounds.
2. To determine if relationships between sensory modulation and the identified risk factors could be explained by an exploratory path analysis model.
3. To explore changes in the relationships between sensory modulation and identified risk factors when the variable lead exposure is included as an additional risk factor in a second exploratory path analysis model for a part of the sample.

About the First Research Aim

Prevalence of SMD

It was hypothesized that prevalence rates determined in this study would be higher than those reported in previous research with children from the US mainland. This hypothesis was supported. The prevalence of SMD in the total sample of this study (n=141), indicated by those with scores classified under the definite difference category of the SSP, was 19.9% (n=28). This is higher than percentages found in studies

conducted on the US mainland. Estimated rates of sensory processing disorders among kindergarteners from a suburban public school district using the SSP were 13.7% (Ahn, Miller, Milberger & McIntosh, 2004). More recent findings from a sample of elementary school-aged children indicated a prevalence of 16% (Ben-Sasson, Carter & Briggs-Gowan, 2009). There are also some important differences between this study and the cited studies. For example, the sample size of this study ($n = 141$) was smaller than sample sizes of previous studies ($n = 703$, Ahn, et al., 2004; $n = 925$, Ben-Sasson, et al., 2009). This may imply lower variability and representativeness of this study sample in comparison with the samples of previous studies.

Further, the instrument used to measure sensory processing by Ben-Sasson, et al. (2009) was the Sensory Over-responsivity (SOR) questionnaire. While the SOR and the SSP both include items related to all sensory domains and are intended to measure sensory modulation during daily life, they have inherent differences. In contrast to the SOR, the SSP does not provide overall scores for sensory over or under responsivity. Instead, scores are summed into one total thought to be reflective of SMD. In addition, in the study by Ben-Sasson et al. (2009), emphasis was given to the auditory and tactile modalities, as these are most frequently reported. Therefore, the 16% prevalence rate reported by Ben-Sasson and colleagues may be an under-estimate of SMD in the population due to their consideration of only tactile and auditory SOR scores. Findings from the current study, however, did indicate that domains of the SSP with the higher percentage of participants under the definite difference classification were Underresponsive/Seek Sensation (38.3%), Tactile sensitivity (17.0%), and Auditory

filtering (15.6%). This supports the possibility of a higher incidence of tactile and auditory issues among children with SMD.

It is important to note that in the current study, the percentage of children under the definite difference category in the Underresponsive/seeking sensation section of the SSP (38.3%) was slightly higher than the percentage of those under the typical performance category (37.4%). A study that assessed differences in sensory related behaviors measured by the SSP between children with Autism Spectrum Disorders and children with SMD found that, in addition to auditory filtering, the second most significant symptom of those with SMD was Sensory Seeking (Schoen, Miller, Brett-Green, & Nielsen, 2009).

Additionally, parents' perceptions about desired behaviors of their children differ among cultures and might influence responses to self-reporting measures. For example, there is evidence that relative to Anglo-Americans mothers, Puerto Rican mothers place more emphasis on their children abilities to maintain proper respect and demeanor and less emphasis on individual autonomy. Puerto Rican mothers value child behavior that could be described as calm, obedient, and well brought up (Arcia, Reyes-Blanes, & Vázquez-Montilla, 2000; Harwood, Schoelmerich, Ventura-Cook, Schulze, & Wilson, 1996). It is possible that Puerto Rican mothers have higher expectations of their children in terms of behaviors related to their activity level (as opposed to the desired calm behaviors described in the cited studies). It should be noted that on the SSP, items in the Underresponsive/Seeks Sensation section are particularly related to activity levels (e.g., item 17- Becomes overly excitable during movement activity; item 18- Touches people

and objects; item 20- Jumps from one activity to another so that it interferes with play) and, therefore it might be more impacted by mothers' beliefs about desired behaviors. This could explain the high percentage of children under the definite difference category on this section.

Another aspect to consider when explaining the high percentage of children under the definite difference category in the Underresponsive/seeking sensation area is the adequacy of the SSP as a measurement tool for children 3 to 5 years. The Sensory Profile (1999) in its full version provides different cut scores for children under this age group, which are not provided for by the SSP. Indeed, users of the full Sensory Profile are advised to conduct further assessment for children 3 to 4 years old when their scores fall into the definite difference range. It is understood that some of the behaviors included in the SSP, especially those related to sensation seeking, could be considered typical for preschool children such as "Becomes overly excitable during movement activities" (item 17), and "touches people and objects" (item 18).

Similar results (i.e., high percentage of children under the definite difference category in the Underresponsive/seeking sensation domain) were found in a previous study that also had preschoolers' parents as participants (Reynolds, Shepherd, & Lane, 2008). Researchers pointed to the possibility that parents might have not comprehended that the SSP was asking about behaviors that exceed the norm; this could also have been the case in this study. Although a supplemental form with clarification of some of the items was provided to parents of this study, it is possible that some had not used the form or still had doubts regarding some of the items that were not clarified in the form. In any case,

following Dunn's advice (1999), scores obtained by preschoolers of this study must be interpreted with caution.

Socioeconomic Status

It was hypothesized that sensory modulation abilities would be lower (indicated by lower scores in the SSP) among preschoolers whose caregivers had lower educational degrees and lower household incomes. This hypothesis was not supported. Findings indicate no significant differences in SSP scores between preschoolers' from low and high SES groups. These findings contradict literature pointing to the potential relevance of socio-economic factors when assessing prevalence of sensory modulation disorders. Ben-Sasson, et al. (2009) found that children with elevated scores in sensory over-responsivity were more likely to be of minority ethnicity, living with a single parent and/or a non-employed parent, and were of lower SES than children with low sensory over-responsivity scores.

Variability of the sample of this study (n=141) compared to Ben-Sasson's et al. (2009) study (n=925) must be considered when discussing this point. First, variability of the sample of this study is limited by its homogeneity and relatively small sample size. In addition, one relevant indicator of SES used by Ben-Sasson and colleagues (2009) was the percentage of participants who received poverty assistance, which was approximately 16%. Characteristics considered in this study to define SES were different from the study by Ben-Sasson's et al. (2009). Participants were not asked whether or not they received poverty assistance. However, 34.7% of the participants in this study reported a household income of less than \$10,000. Indeed, poverty guidelines from the US Census Bureau

(2008) indicate that a family of four with a household income lower than \$22,025 is considered to be below the poverty threshold. According to the characteristics of the sample of this study (see Table 6), approximately half of the sample (51.7%) would meet this criteria and might be receiving poverty assistance. Due to this low variability in income, differences between high and low income groups may not have been possible to observe. Thus, the variability of this sample relative to SES should be considered carefully when assessing how SES influences the prevalence of SMD.

In summary, the first aim of this study was to establish the presence and examine the prevalence of SMD in a sample of Puerto Rican preschoolers from different SES backgrounds. The first hypothesis was supported: prevalence rates of this study were higher than those reported in previous studies with children from the US mainland. The second hypothesis was not supported. No significant difference was observed in SMD (SSP total scores) based on the educational degree and household income of parents.

About the Second and Third Research Aims

The second aim of this study was to determine if relationships between sensory modulation and identified risk factors could be explained by an exploratory path analysis model. The third aim was to explore changes in those relationships when the variable lead exposure was included as an additional risk factor in a second path analysis model. It was not possible to fully assess the first hypothesis related to these aims, which stated that moderate relationships would be observed between SES and prenatal alcohol exposure, SES and prenatal nicotine exposure, and SES and lead exposure. This was due to the elimination of the variables prenatal alcohol exposure and prenatal nicotine

exposure from the analyses (see the section “Preparation of the database” in Chapter Three). It was also not possible to directly assess the relationship between the variables SES and lead due to required modifications made to the path analysis models initially proposed. However, the proximity among the variables education, household income, and lead determined by the cluster analysis performed for the Head Start sample, suggest the possibility of a relationship between these variables. Nonetheless, analyses did not provide enough evidence to determine retention or rejection of this hypothesis.

The second hypothesis corresponding to these aims indicated that SES and prenatal alcohol exposure would be the variables with the higher directional linear associations with SMD (as long as lead exposure was not considered as part of the path analysis model). Due to the previously mentioned elimination of the variable prenatal alcohol exposure, this hypothesis could not be fully tested. As explained in Chapter Four, it was not possible to include SES in the path analysis model as a latent variable composed by education and household income. Instead, both variables (education and household income) had to be included separately in the model. Findings partially supported the hypothesis of SES having a linear association to SMD. Results of the SEM for the total sample pointed to income as the variable with the higher association to sensory modulation (in comparison with the other variables), followed by birth weight and education (both variables showed similar regression weight values indicating similar relative importance).

The third hypothesis was assessed using only data from the Head Start sample. It stated that once lead exposure was included as part of the analysis, SES and lead

exposure would be the variables with the higher directional linear associations with SMD. This hypothesis was also partially supported. The variable lead was the one with the highest relative importance in the SEM, but depending on the estimation technique used (maximum likelihood vs. Bayesian approach), it was followed by education and then income (maximum likelihood) or by birth weight (Bayesian approach). It should be noted that this information, as well as the one related to the previous hypothesis, is based on regression weights (that indicate relative importance of variables) obtained through the SEM analyses performed. Although they allow the assessment of the relative importance of variables, all regression weight values were low. Thus additional analyses were needed in order to further explore relationships between risk factors and sensory modulation. Additional results and limitations found are discussed next.

Model Fit

Path analysis using SEM was used to examine relationships between the identified risk factors and scores on the SSP. The first step when using SEM is the assessment of the model fit. This is important because it indicates if the relationships designated among the variables in the model (i.e., the directions of the arrows in the model) were an adequate representation of the way they were associated with each other. Models were assessed both for the total sample (without the variable lead exposure) and for the sample of Head Start children (including the variable blood lead level). Also, models were re-specified twice in order to comply with the principle of parsimony. Models with the best fit indexes are shown in Figures 16 and 19 of Chapter Three. For example, in the case of the model for the total sample (Figure 14) a non-significant X^2 of

1.82 and a NFI of 0.98 were indicators of the good fit of the model. As well, for the model of the Head Start sample (Figure 17), a X^2 of 6.15 and a NFI of 0.70 supported its adequate fit. This means that both models were able to explain the relationship between the included risk factors and SMD, giving an affirmative answer to research questions 2.1 and 3.1 (see Table 3 in Chapter Three).

Regarding research questions 2.2 to 3.3, the percentage of variance explained by the models was low (.9% for the model of the total sample, and .5% for the model of the Head Start sample). These low percentages indicate that, despite the fit, proposed models were not useful in explaining the variance in SSP scores as the literature review suggested. This was an unexpected finding, since previous research pointed to the significance of included risk factors. One aspect that might have influenced this result was the inability to analyze path analysis models as originally proposed. It should be recalled from Chapter Three that due to issues with assumption compliance, the variables “prenatal alcohol exposure” and “prenatal nicotine exposure” were eliminated from the models analyzed. In addition, as explained in Chapter Four, original models were modified in order to achieve the most parsimonious solutions. Thus, although models finally analyzed included most of the risk factor variables identified in the literature review, essentially they were not the models initially proposed and, thus, did not reflect the relationships among variables originally conceptualized based on previous research findings.

It should be added that low variances also point to the need to consider other factors in order to better explain the prevalence of SMD. Recent studies have pointed to

additional risk factors that might be associated to SMD (Goldsmith, Van Hulle, Arneson, Schreiber, & Gernsbacher, 2006; Keuler, Schmidt, Van hulle, Lemery-Chalfant, & Goldsmith, 2011; May-Benson, Koomar, & Teasdale, 2009; Reynolds, et al., 2008; Schneider, et al., 2007; Van Hulle, Schmidt, & Goldsmith, 2012). In addition to socioeconomic and environmental variables, studies have also looked at pre, peri and post natal variables. May-Benson, et al. (2009) found that reports of history of maternal stress during pregnancy, fetal distress, jaundice, and significant childhood illnesses such as chronic ear infections were higher in children with sensory processing disorders.

Besides, genetic factors have been considered in recent studies with twins. Sensory over-responsivity (SOR), specifically tactile and auditory SOR, has been the focus of these studies. One study used a population-based sample of 1394 toddler age twins, whose mothers reported on tactile and auditory defensiveness, among other measures. Statistical analyses suggested moderate genetic influences. For auditory defensiveness, 38% of the variance was explained by genetic; while for tactile defensiveness, genetic influence accounted for 52% of the variance. Researchers asserted that the tactile domain might be more heritable than the auditory domain (Goldsmith, et al., 2006). Subsequent studies have shown similar results. Keuler's, et al. (2011) findings suggest that auditory and tactile SOR are heritable and share some degree of both genetic and environmental variances. Additionally, Van Hulle, et al. (2012) examined the comorbidity between childhood psychopathology and SOR using a behavior-genetic framework, and found that mothers of children who screened positive for SOR were more likely to report a history of mental illness. Researchers suggest the possibility that

mothers pass on genes related to SOR and psychopathology symptoms, but recognize that it is also possible that mothers with a history of mental illness might be biased toward endorsing SOR symptoms.

Among the other risk factors that might be considered to explain SMD, maternal stress during pregnancy may deserve additional attention. Studies linking maternal stress to SMD have been feasible only through use of primate models (Schenider, et al., 2007) or retrospective chart review (May-Benson, et al., 2009). Challenges exist in human retrospective studies due, in part, to the inherent reliability issues associated with subjects reporting on past events, and to the need for a standard definition of the concept “stress” that can be used consistently across different studies (i.e., what is considered maternal stress during pregnancy?).

Some challenges in design can be overcome through the use of prospective experimental studies using animal models. Scheneider, et al. (2008) investigated the effects of prenatal stress exposure on tactile withdrawal responses (aversion) and habituation to repeated tactile stimulation in a cohort of rhesus monkeys. Prenatally stressed monkeys were birthed by mothers that experienced a daily 10 minute stressor (10 minute removal from home cage and exposure to three random noise blasts) during gestational days 90 – 145. Findings indicated that monkeys born to non-stressed mothers showed the expected behavioral pattern of habituation across trials, while exposure to prenatal stress induced slight behavioral sensitization. As a possible explanation of their findings, researchers alluded to previous evidence suggesting that, although mechanisms underlying the developmental sequels of prenatal stress have not been completely

determined, there is evidence that maternal stress hormones can cross the placental barrier.

To summarize, the fact that the models analyzed in this study showed an adequate fit implies that they represent appropriate ways of constructing relationships between the variables included or available (after considering compliance with analysis assumptions). However, the low percentages of explained variance for sensory modulation suggests that the models and relationships included in them are not sufficient to explain SMD. While future studies should consider additional risk factors, along with methodologies that allow for the examination of the complex relationships among them, there is still information to be gleaned about risk factors that were most relevant to SMD in the current study.

Most Relevant Risk Factors Identified in this Study

A series of analyses were performed to determine the most relevant risk factors among those included in this study. Results of the SEM pointed to income as the most important factor for the total sample, while blood lead level (BLL) was the most relevant factor for the Head Start sample. Nonetheless, given the low percentages of variance explained by all the risk factors included in the model, additional analysis were conducted to further explore the data and assess whether the variables related with SMD as previously suggested in the literature.

One such analysis included a series of ANOVAs using the sections of the SSP as dependent variables and each of the risk factors as independent variables. It was found that Movement sensitivity and Underresponsive/seek sensation for the total sample were

different based on the amount of education of the parents. Differences on the Movement sensitivity section were identified between participants with educational degrees of eighth grade or less and those with a bachelor's degree or graduate degree. Additionally, differences on the Underresponsive/seeking sensation section were found between individuals with some college courses and those with a graduate degree. In both sections (Movement sensitivity and Underresponsive/seeking sensation), differences indicate that children whose parents had higher educational degrees were rated higher than those with lower education.

This information is in line with previous studies suggesting a possible relationship between factors related to SES (such as educational level) and prevalence of SMD. Ben-Sasson et al. (2009) found that children with sensory over-responsivity were more likely to be of lower SES. Another study with a sample of urban African-American children from low income households indicated that they were two and a half to three times more likely to meet the criteria for SMD, when compared to previously reported data of typically developing Caucasian children (Reynolds, et al., 2008).

Data about educational levels tend to be reported in association with income and other variables related to SES. The differences found in this study between subjects with higher and lower educational degrees may be associated with differences in access to enriched environments. Studies have indicated that lower SES homes are associated with less rich home environments that limit the child's exposure to stimulating toys and materials. In addition, stress levels in lower SES homes tend to be higher, while the attention and responsivity of adults to the child's needs tend to be lower. All these aspects

have been associated with poorer psychomotor and cognitive outcomes (Soler-Limón, Rivera-González, Figueroa-Olea, & Sánchez-Pérez, 2007; Sarsour, Sheridan, Jutte, Nur-Jeter, Hinshaw, & Boyce, 2010). No study has been published about the relationship among SES, home environment, and the development of sensory processing abilities of the child. However, this is an area that could be further explored in future studies.

Another section of the SSP, Tactile sensitivity, was significantly different for the total sample based on the risk factor “birth weight.” This was similar for the Head Start sample, although differences did not reach the established level of significance ($p = .057$). In both cases (total sample and Head Start) the tendency was that children whose mothers reported lower birth weights were more likely to obtain lower scores (indicating greater dysfunction) in the Tactile sensitivity section of the SSP. Studies that have looked at both low birth weight and pre-term infants suggest the presence of tactile sensory modulation issues (Weiss, 2005), and that these behaviors may carry over into later childhood (Walker, et al., 2009). It has been proposed that hospitalizations of pre-term and low birth weight infants may limit their exposure to tactile experiences, especially to socio-emotional touch (Weiss, 2005).

Risk Factors According to Children Regulatory Mechanisms

Additional analyses included a factor analysis to identify those factors formed by sections of the SSP used as dependent variables in MANOVAs. Contrary to what had been expected in the factor analysis, sections of the SSP did not group according to a pattern of high or low threshold (over and under responsivity), which are the guides typically used in the research literature about sensory modulation (Miller, et al., 2007;

Dunn, 1999). Instead, for the total sample and the Head Start sample, grouping of the sections was better explained by the regulatory mechanisms that children seemed to use. Thus, factors were labeled “seeking as a regulatory mechanism” (SRM), and “passive response as a regulatory mechanism” (PRM).

These patterns are similar to the self-regulation strategies (behavioral responses) proposed in Dunn’s Model of Sensory Processing (2006), presented in Figure 20.

Neurological Threshold Continuum	Behavioral response/ Self regulation continuum	
	Passive	Active
HIGH (Habituation)	Low Registration	Seeking
LOW (Sensitization)	Sensitivity	Avoiding

Figure 20. Dunn’s Model of Sensory Processing (Dunn, 2006)

Dunn’s model helps to conceptualize the contribution of sensory processing to a child’s behavior by hypothesizing an interaction between neurological thresholds and behavioral responses. The first column of the model refers to the neurological threshold (high or low) or the amount of stimuli needed for a child to notice or react to it. The behavioral responses or self regulation continuum (passive or active) indicate the manner in which a child responds to the stimuli (Brown & Dunn, 2010). In Dunn’s model (Brown & Dunn, 2010), neurological thresholds and behavioral responses interact, forming the following sensory processing patterns:

- Low Registration – described as the degree to which a child misses sensory input (high neurological threshold and passive response)

- Seeking – degree to which a child obtains sensory input. Indicates an excessive need for sensation. These children also have a high neurological threshold, but respond actively.
- Sensitivity – degree to which a child notices sensory input (low neurological threshold and passive response)
- Avoiding – degree to which a child is bothered by sensory input (low neurological threshold and active response)

Factors identified in this study using the sections of the SSP (seeking as a regulatory mechanism – SRM – and passive response as a regulatory mechanism – PRM) are consistent with the active and passive strategies presented by Dunn (2006). In Dunn's model, children in the Low registration and the Sensitivity quadrants are thought to use passive behavioral responses mechanisms, while those in the Seeking and Avoiding quadrants are thought to use active mechanisms for regulation. Given that the short version of the Sensory Profile was the one used in this study, it was not possible to categorize children's responses to sensory stimuli according to the sensory processing patterns identified in Dunn's model. Nonetheless, although results of this study are exploratory in their nature, future studies can further explore sensory modulation processes of children in terms of self regulatory mechanisms used, along with the type of response (over or under responsivity) to daily sensory stimuli.

Results of the MANOVAs performed using the factors SRM and PRM as dependent variables and the risk factors as independent variables were not significant. Risk factors birth weight and education obtained the lowest p values for the total sample,

while for the Head Start sample, blood lead levels, birth weight and education were the variables with the lowest p-values. These results corresponded to the findings of the SEM using Bayesian estimation, except that in the case of the total sample, the variable with the higher relative relevance in the SEM was income, followed by birth weight and education. Despite these trends, the percentage of variance explained by the factors was very low. Literature about the relevance of socioeconomic variables and birth related variables has already been discussed. Evidence about the possible relationship between SMD and lead exposure come primarily from studies using primate models (Moore, et al., 2008; Scheneider et al., 2007). These studies indicate that lead-exposed monkeys showed significantly more tactile defensiveness responses to repeated tactile stimuli compared with monkeys not exposed to lead. Additionally, Moore et al. (2008) found that lead exposure measured during early life (first three months) was positively correlated to the magnitude of tactile defensiveness.

The current study is the first providing some exploratory evidence about lead exposure and SMD in human subjects. The percentage of variance in SSP scores explained by blood lead levels in this sample was low. However, there are some aspects and limitations of this study that must be considered when interpreting the results. First, data about blood lead levels in the children was obtained from results available in their records as part of the procedures completed to enter the Head Start program. Thus, there are limitations inherent in the use of retrospective data. One was the presence of missing values, which led to the performance of a missing value analysis with data imputation (see section Preparation of the data base in Chapter Three). Despite its advantages, the

performance of data imputation, as well as the use of a secondary data source, imposes some limitations in terms of the reliability of the collected information.

Additionally, considerations about the use of blood lead levels as a measure of lead exposure must also be mentioned. Although blood tests are the most common method used to monitor lead exposure, they are better indicators of short term exposure (i.e., past months) vs. long term exposure (Bergdahl, & Skerfving, 2008; Committee on Measuring Lead in Critical Populations, Board on Environmental Studies and Toxicology, & Commission on Life Sciences, 1993). The data collected represents the blood lead levels of the children during the months prior to data collection (at the beginning of Head Start). This is especially important considering Moore's et al. (2008) finding that lead exposure during early life was positively correlated to the magnitude of tactile defensiveness in monkeys. Potentially, blood lead levels taken very early in life would be more strongly related to SSP scores in early childhood. This would align with the general assumption that early teratogenic insults can have lasting effects on the behavior of children. To study long term effects of lead exposure, teeth or bone biomarkers would be preferable (Bergdahl, & Skerfving, 2008). However, these were not feasible for this study.

Finally, the sample size of the Head Start group (for whom data about blood lead levels was collected) limits the power and effect sizes of the statistical analyses performed ($n = 78$). Observed power of reported MANOVA analyses ranged from .28 to .63, while effect sizes (determined by partial eta squared) were all small, ranging from .02 to .05. According to Cohen's (1988) guidelines of effect sizes, an eta squared near to

.09 indicates a medium effect size. Considering the quantity of groups in the performed MANOVAs ($k = 64$, two levels for the blood lead level variable, two levels for birth weight, four levels for income, and four levels for education), and the two response variables formed by the factors SRM and PRM, a sample size of 320 subjects would have been needed to reach a moderate effect size of .10, with an alpha of .05, and a power of .80. This was calculated using the program G*Power 3.1.2 (2009). As mentioned, the sample size of subjects with data of blood lead levels available was 78. However, previously outlined limitations should not diminish the importance of the study of variable lead exposure in relation to SMD. The fact that some relevancy was observed despite limitations of the data is indicative that it is a factor that should be further investigated.

Study Limitations

Some of the limitations of this study regarding the way lead exposure was measured have already been discussed. Other important limitations were the sampling strategy and sample size. Participants of this study were all recruited through convenience sampling. This, as well as the sample size, limits the variability of the sample; thus the generalizability of the results is limited. One specific aspect that affected variability was that not all preschool centers initially identified agreed to participate in the study. Specifically, private centers identified because of their location in more affluent areas, denied access to the researcher. Thus, while other private centers did agree to participate, these were in less affluent areas. This made the sample more homogeneous

and may have had an impact on some of the analysis performed (e.g., analysis of differences based on SES).

Also, as discussed previously, a larger sample size would have: enhance variability of the sample, enhance statistical power, and allow the inclusion of latent variables in the path analysis models. This would permit the assessment of structural equation models with relationships more similar to the ones originally conceptualized, and would positively impact the validity of the results of this study. Moreover, as discussed in the previous section, due to the nature of some of the statistical analyses performed, a greater sample size would have enhanced statistical power and therefore, reliability of the results.

There are some additional limitations that might have affected the validity of the data collected. Although the Cronbach's Alpha coefficient calculated based on the data of this study indicated adequate reliability (.74), it must be pointed out that the tool used to identify SMD (the Spanish version of the Short Sensory Profile), has not been validated for the Puerto Rican population. While the cognitive interviews were performed as a means to reduce the impact of cultural and/or language differences (see the section "Strategies applied prior to data collection of the study" on Chapter Three), no specific strategy was implemented to verify if participants used and/or understood the clarifying guidelines provided to them. It is recognized that the use of a tool validated for the Puerto Rican population to identify sensory modulation issues would have enhanced the validity of information provided by the participants. However, such a tool is currently unavailable.

Second, reliance on self-reporting measures to collect data about most of the risk factors and SMD might have added some bias related to respondents' memory and, especially to the person's tendency to conceal information that he/she believe could be considered inappropriate (Polit & Beck, 2008). This is likely the case for the risk factors alcohol consumption and smoking during pregnancy, as suggested by the extremely low quantity of participants who reported these behaviors. The frequency and rate of these behaviors was much less than has been reported in prior household surveys indicating, for example, that 31.8% of females in Puerto Rico who had been pregnant at some point during the 12 months prior to the study reported that they consumed alcohol during the same period (Mental Health and Anti Addiction Services Administration of Puerto Rico, 2002). The fact that 10/12 participants who indicated alcohol consumption were from private preschools further suggests differences in the current sample, since alcohol use and smoking during pregnancy have traditionally been higher in low SES groups.

It is believed that two different types of bias might have affected participants' report of smoking and alcohol consumption during pregnancy in this study. The first one was bias associated with the intent of reporting what might have been considered as desired behaviors; and secondly, it is possible that Head Start mothers fear that their responses could affect services they received from the Head Starts. These concerns might have occurred despite the orientation presented in advance of the study and the consent process in which all subjects participated.

The limitations identified suggest that caution should be employed when interpreting the results of this study. The limitations, however, do not detract from the

contribution that this exploratory study has as a preliminary effort to characterize the relationship between SMD and associated risk factors. Nonetheless, consideration of the limitations mentioned will enhance the validity and reliability of findings of future studies.

Conclusions, Future Directions, and Implications for Practice

Providing a definite response about the most relevant risk factors for SMD base on the results of this study is not possible due to its limitations and scope. Results obtained point to the possible general relevancy of income and birth weight for the total sample, and lead exposure and birth weight, followed by income for the Head Start sample. However, low effect sizes and low percentages of shared variances among variables indicate that despite the strong links between risk factors and SMD suggested in the literature review, findings do not support such strong associations. In terms of relative importance among variables, results provide some evidence about the possible relevance of socio-economic and birth related factors when analyzing the potential variables related to SMD, which has been supported in previous studies (Ben-Sasson, et al., 2009; May Benson, et al., 2009, Reynolds, et al., 2008). Results did not fully support nor discard the potential relevance that environmental toxins, such as lead exposure, might have when they are also considered among those variables. Theoretically and methodologically, the research points to the pertinence of taking into account the possible convergence between individual, social and community risk factors, not only to explain SMD, but also to identify populations more vulnerable to the disorder.

Findings strongly suggest that there are additional unknown factors that might be associated with the presence of SMD. Based on the literature, it is suggested that future studies consider additional factors such as other birth related variables (May-Benson, et al., 2009), maternal stress levels during pregnancy (Scheneider, et al., 2008), and genetic variables (Goldsmith, et al., 2006; Keuler, et al., 2011; Van Hulle, et al., 2012). In order to reduce the impact of limitations found in this study, additional aspects that should be taken into account are: (1) implementation of strategies to enhance reliability of data regarding the variables alcohol consumption, smoking during pregnancy, and children lead exposure; and (2) the validation of a tool to identify SMD for the Puerto Rican population.

It is believed that the respondent's tendency to *not* report behaviors that might be considered inappropriate (e.g., alcohol consumption and smoking during pregnancy) was the bias that most affected the reliability of the variables. The inclusion of mothers who have participated in alcohol and/or nicotine abuse rehabilitation programs while pregnant could help to overcome this limitation. Limitations related to the reliability of lead exposure data might be ameliorated by the use of prospective (current) blood lead levels instead of the use of record review. Ideally, longitudinal studies would allow the collection of data during pregnancy and after the child's birth. Blood samples taken periodically during the first few years of life would provide information about early exposure to lead. This would be of particular importance since, as discussed, there is reason to believe that early exposure might be more strongly related with sensory modulation behaviors during early childhood (Moore et al., 2008).

Another way to enhance reliability of the data would be the use of a tool validated for the Puerto Rican population to measure SMD. Currently, the only tool available in Spanish is the Sensory Profile. Validation of this or other instrument would entail the adaptation of that instrument. Test adaptation is broader than test translation. It refers to the process of preparing a test that is constructed in one language and culture for use in a second language and culture. It includes activities such as deciding whether or not a test could measure the same construct in a different language and culture, selecting translators, deciding on appropriate accommodations to be made in preparing the instrument for use in a second language, and adapting the test and checking its equivalence in the adapted form (Hambleton, 2005). Validation of the tool comes after adaptation and requires the completion of pilot and subsequent studies that contribute to broad the evidence of the tool validity. Studies to adapt or elaborate and validate a measure of sensory modulation for the Puerto Rican children must be considered as part of the design of future research projects.

Additionally, future studies should still consider the use of statistical techniques, such as path analysis, that allow the assessment of complex interactions between the potential risk factors that might explain SMD. Larger and more heterogeneous samples are recommended in order to achieve adequate power when applying such statistical analyses. Future studies could also consider the use of qualitative methods of data collection with mothers of children with SMD. Qualitative analysis could be used to get a deeper and more detailed understanding of families' current and past contextual factors as

well as pregnancy history; this data could then be subsequently used in the design of more specific objective quantitative studies.

Although more research is required to further understand SMD, this study adds information to the body of knowledge available about its prevalence and possible causes. As professionals with a broad understanding about the impacts that SMD has on a child's ability to fully participate in their daily occupations, occupational therapists are in an ideal position to bring necessary attention to SMD through education and advocacy efforts. Awareness of aspects such as prevalence and potential risk factors associated with SMD may help occupational therapists working both at the individual and community levels, and assist in directing intervention efforts to more vulnerable populations. This is of particular importance for the Puerto Rican population, since no study has been done before to determine the prevalence of SMD, although Puerto Rican children seem to be in a position of vulnerability as reflected by the higher rate of preschoolers having SMD (when compared to prevalence rates of previous studies in the US Mainland), and by their minority status and the social and economical variables associated with minorities.

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APPENDIX A: DEMOGRAPHIC AND RISK FACTORS DATA SHEET (ENGLISH
AND SPANISH VERSIONS)

Sensory Modulation Disorder in Puerto Rican preschoolers: Associated risk factors

Demographic and risk factors data sheet

Note: Responses to the following questions will be used exclusively for research purposes. You are not obliged to provide information about any subject/question that discomforts you. However, information provided will be managed confidentially. Your completion of this form will not impact services you and/or your child is currently receiving or will receive in the future.

Please, answer the following questions providing the information asked or writing a check mark (☒) in the space that corresponds to your answer.

1. How old is your child? (Please indicate years and months)

_____ years and _____ months

2. Mark the child's gender.

☐ Female ☐ Male

3. Who is(are) the primary caregiver(s) of the child?

☐ Mother and father ☐ One parent and one grandparent
☐ Mother only ☐ Uncle/aunt
☐ Father only ☐ Other; please specify _____
☐ Grandparents

4. Please, indicate the educational level of the primary caregiver(s) of the child.

Below, indicate the relationship of the caregiver with the child (e.g., mother, father, grandfather, aunt):

Indicate the highest educational level achieved by the person mentioned above

☐ 8th grade or less
☐ 9th – 12th (no high school diploma)
☐ Graduated from high school or equivalent program
☐ Some college courses (not completed degree)
☐ Certificate
☐ Associated degree
☐ Bachelors degree
☐ Graduated degree (master or doctoral)

Below, indicate the relationship of the caregiver with the child (e.g., mother, father, grandfather, aunt):

Indicate the highest educational level achieved by the person mentioned above

☐ 8th grade or less
☐ 9th – 12th (no high school diploma)
☐ Graduated from high school or equivalent program
☐ Some college courses (not completed degree)
☐ Certificate
☐ Associated degree
☐ Bachelors degree
☐ Graduated degree (master or doctoral)

5. Mark the range that best represents your household income.

- | | | |
|--|--|--|
| <input type="checkbox"/> less than \$10,000 | <input type="checkbox"/> \$35,000 - \$49,999 | <input type="checkbox"/> \$100,000 - \$149,999 |
| <input type="checkbox"/> \$10,000 - \$14,999 | <input type="checkbox"/> \$50,000 - \$74,999 | <input type="checkbox"/> \$150,000 - \$199,000 |
| <input type="checkbox"/> \$15,000 - \$24,999 | <input type="checkbox"/> \$75,000 - \$99,999 | <input type="checkbox"/> more than \$200,000 |
| <input type="checkbox"/> \$25,000 - \$34,999 | | |

6. Mark the range that corresponds to the child's weight when he/she was born.

- ☐ 3.3 pounds or less (very low birth weight)
☐ 3.4 - 5.5 pounds (low birth weight)
☐ 5.6 pounds or more (normal birth weight)
☐ Other, please comment: _____

7. How many weeks of pregnancy the mother had when she gave birth?

- ☐ 36 weeks or less (preterm)
☐ 37 weeks or more (full term)
☐ Other, please comment: _____

8. Which best describes the pattern of alcohol consumption of the mother during pregnancy?

- | | |
|--|---|
| <input type="checkbox"/> Every day | <input type="checkbox"/> 2 to 3 times a month |
| <input type="checkbox"/> Near every day | <input type="checkbox"/> Once a month |
| <input type="checkbox"/> 3 to 4 times a week | <input type="checkbox"/> A few scattered occasions during pregnancy |
| <input type="checkbox"/> 2 times a week | <input type="checkbox"/> Never |
| <input type="checkbox"/> Once a week | |

9. On any one occasion during pregnancy, did you consume more than 5 drinks? (Consider all types of alcoholic beverages - i.e., beer, wine, cordial, etc.)

- ☐ Yes ☐ No

10. How many cigarettes did the child's mother smoke during pregnancy on an average day? (A pack has 20 cigarettes)

- | | |
|---|--|
| <input type="checkbox"/> over 20 cigarettes per day (more than a pack) | <input type="checkbox"/> 1-10 cigarettes per day (half a pack or less) |
| <input type="checkbox"/> 11-20 cigarettes per day (more than half a pack) | <input type="checkbox"/> None (0 cigarettes) |

11. Has your child been diagnosed with any of the following conditions?

- ☐ Any Pervasive Developmental Disorder (Autism, Rett's Disorder, Asperger, PDD-NOS)
☐ Attention Deficit Hyperactivity Disorder (ADHD)
☐ Down syndrome
☐ Fetal Alcohol Syndrome (FAS)
☐ Any motor/movement impairment
☐ Other condition: _____
☐ Does not have any diagnosis

Thanks for the information provided.

Certificate of Translator

I, Rafaela Mena, of legal age, resident of San Juan, Puerto Rico, registered pharmacist in Puerto Rico with license number 2313, and professional translator accredited member in good standing of the American Translators Association, HEREBY CERTIFY that, to the best of my knowledge and abilities, the foregoing document, **Social and Demographic Questionnaire**, is a true and faithful rendering into English of the original Spanish text which I have seen, as described herein.

In San Juan, Puerto Rico, today, **June 16, 2010**



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Desorden de Modulación Sensorial en niños preescolares puertorriqueños: Factores de riesgo asociados

Hoja de datos demográficos y factores de riesgo

Nota: Sus respuestas a las siguientes preguntas se utilizarán solamente para propósitos investigativos. Usted no está en la obligación de proveer información acerca de cualquier tema/pregunta que pueda incomodarle. Sin embargo, toda la información será manejada de manera confidencial. Completar este cuestionario no tendrá ningún impacto en los servicios que usted o su niño(a) recibe actualmente o recibirá en un futuro.

Por favor, conteste las siguientes preguntas proveyendo la información que se le solicita o haciendo una marca de cotejo (☑) en el espacio que corresponda a su respuesta.

1. ¿Qué edad tiene su hijo(a)? (por favor indique edad en años y meses)

_____ años y _____ meses

2. Marque el género de su hijo(a).

☐ Femenino

☐ Masculino

3. ¿Quién/quienes son los cuidadores principales del niño(a)?

☐ Mamá y papá

☐ Uno de sus padres y un(a) abuelo(a)

☐ Mamá solamente

☐ Tío(a)

☐ Papá solamente

☐ Otro; por favor, especifique _____

☐ Abuelos

4. Por favor, indique el nivel educativo del cuidador(es) principal(es) del niño(a).

En la línea indique el parentesco del cuidador con el niño(a) (ej. mamá, papá, abuelo, tía):

En la línea indique el parentesco del cuidador con el niño(a) (ej. mamá, papá, abuelo, tía):

Indique el nivel educativo más alto alcanzado por la persona mencionada en la línea

☐ 8^{vo} grado o menor

☐ 9^{no} – 12^{mo} (sin diploma de escuela superior)

☐ Graduado de escuela superior o programa equivalente

☐ Algunos cursos de universidad (sin completar grado)

☐ Certificado profesional

☐ Grado asociado

☐ Bachillerato

☐ Nivel graduado (maestría o doctorado)

Indique el nivel educativo más alto alcanzado por la persona mencionada en la línea

☐ 8^{vo} grado o menor

☐ 9^{no} – 12^{mo} (sin diploma de escuela superior)

☐ Graduado de escuela superior o programa equivalente

☐ Algunos cursos de universidad (sin completar grado)

☐ Certificado profesional

☐ Grado asociado

☐ Bachillerato

☐ Nivel graduado (maestría o doctorado)

5. Marque el rango que mejor indica el ingreso de su hogar.

- | | | |
|--|--|--|
| <input type="checkbox"/> Menos de \$10,000 | <input type="checkbox"/> \$35,000 - \$49,999 | <input type="checkbox"/> \$100,000 - \$149,999 |
| <input type="checkbox"/> \$10,000 - \$14,999 | <input type="checkbox"/> \$50,000 - \$74,999 | <input type="checkbox"/> \$150,000 - \$199,999 |
| <input type="checkbox"/> \$15,000 - \$24,999 | <input type="checkbox"/> \$75,000 - \$99,999 | <input type="checkbox"/> Más de \$200,000 |
| <input type="checkbox"/> \$25,000 - \$34,999 | | |

6. Marque el rango que mejor indica el peso de su hijo(a) cuando nació.

- ☐ 3.3 libras o menos (muy bajo peso al nacer)
☐ 3.4 - 5.5 libras (bajo peso al nacer)
☐ 5.6 libras o más (peso promedio al nacer)
☐ Otro. Por favor, especifique: _____

7. ¿Cuántas semanas de embarazo tenía la madre del niño(a) cuando éste(a) nació?

- ☐ 36 semanas o menos (nacimiento prematuro)
☐ 37 semanas o más (nacimiento a término)
☐ Otro. Por favor, especifique: _____

8. ¿Cuál de las siguientes describe mejor el patrón de consumo de alcohol de la madre durante el embarazo?

- | | |
|--|--|
| <input type="checkbox"/> Todos los días | <input type="checkbox"/> 2 a 3 veces al mes |
| <input type="checkbox"/> Casi todos los días | <input type="checkbox"/> Una vez al mes |
| <input type="checkbox"/> 3 a 4 veces a la semana | <input type="checkbox"/> En algunas ocasiones aisladas durante el embarazo |
| <input type="checkbox"/> 2 veces a la semana | <input type="checkbox"/> Nunca |
| <input type="checkbox"/> Una vez a la semana | |

9. En alguna ocasión durante el embarazo, ¿consumió usted más de 5 tragos de uno o varios tipos de bebidas alcohólicas? (Considere todos los tipos de bebidas alcohólicas- ej. Cerveza, vino, cordial, etc.)

- ☐ Sí ☐ No

10. ¿Cuántos cigarrillos fumó la madre del niño durante el embarazo en un día promedio? (un paquete tiene 20 cigarrillos)

- | | |
|---|--|
| <input type="checkbox"/> Más de 20 cigarrillos al día (más de un paquete) | <input type="checkbox"/> 1-10 cigarrillos al día (medio paquete o menos) |
| <input type="checkbox"/> 11-20 cigarrillos al día (más de medio paquete) | <input type="checkbox"/> Ninguno (0 cigarrillos) |

11. ¿Ha sido su hijo(a) diagnosticado con algunas de las siguientes condiciones?

- ☐ Algún Desorden Generalizado del Desarrollo (Autismo, Desorden de Rett, Asperger, PDD-NOS)
☐ Déficit de Atención con o sin Hiperactividad (ADD ó ADHD)
☐ Síndrome de Down
☐ Síndrome de Alcohol Fetal
☐ Algún impedimento motor/de movimiento
☐ Alguna otra condición: _____
☐ No tiene ningún diagnóstico

Muchas gracias por la información ofrecida.

APPENDIX B: CLARIFYING GUIDE TO USE WHILE ANSWERING THE SPANISH
SHORT SENSORY PROFILE (ENGLISH AND SPANISH VERSIONS)

Clarifying guide to use while answering the Spanish Short Sensory Profile (English version)

This guide includes examples related to some of the items that might help you to clarify doubts while answering the Short Sensory Profile. Selection of the items presented has been made based on recommendations offered by other parents/caregivers with whom the questionnaire was discussed.

While answering the questionnaire, try to think about different situations (more than one if possible) in which your child presents the described behavior. Then, answer each question based on the frequency with which those behaviors occur in your child.

Tactile Sensitivity (Items 5, 6, 7)

5. For example, dislikes the upper faucet/shower of the tub, dislikes splashing water from the swimming pool, the feel of rain drops or splashes from a puddle.

6. Dislikes the feeling when other people are too near to him/her; like while waiting in a line, or sitting in a circle time with other children.

7. For example, "cleans" the area where another person kissed him/her or where other children touched him while playing.

Taste/smell sensitivity (Items 9, 10)

9. Think in terms of flavors. For example, think if your child avoids eating sweet or salty food.

10. Think in terms of textures/temperatures. For example, think if your child prefers food that is very hot or very cold; or if he/she will only eat food with certain textures (i.e., only smooth textures-similar to baby food, apple sauce, cream of wheat, mashed potatoes-; or only lumpy foods-like rice or cooked vegetables).

Movement sensitivity (Item 12)

12. For example, while swinging, when carried by an adult, or when climbing on playground equipment (e.g., swings, slides, see-saw).

Under-responsive / seeks sensation (Items 15, 16, 17, 18, 21)

15. For example, he/she likes to hum, whirr or make other noises regardless if he/she is doing a task like drawing or playing with toys.

16. For example, your child seeks out movement opportunities like moving while seated in a chair, jumping on the bed or the sofa, or running down the hallway. This behavior may make completion of routine tasks like having lunch or dinner, getting dressed on time, or doing school tasks (by themselves or with others' help) difficult for the child.

17. For example, he likes movement activities (e.g. jumping, running, swinging) so much that he becomes hyperactive, over aroused, or has difficulty stopping the activity.

18. Think if your child touches either people (even persons they are not familiar with) or objects. For example, your child tends to hug or cling to people, or to take objects in his/ her hands just for the sake of having something to touch.

Auditory filtering (Items 22, 24)

22. For example, while doing some task in the room, your child is easily distracted by the noise of the TV in another room, or by the conversation of others in the room.

24. Background noises refer to those that are part of the place where the child is working or doing an activity (for example, the noise of a fan, the noise from the air conditioner, or the noise from the cars going by the street).

Low energy/ weak (Items 28, 29, 32)

28. For example, your child looks weaker than other children of his/her age.

29. For example, while walking on the street or standing in a store line, your child frequently complains of being tired, or asks you to carry him/her.

32. For example, your child leans on the wall while in a line, or leans/slumps on the desk while doing seated tasks (e.g., coloring or writing).

Visual/ auditory sensitivity (Items 34, 37)

34. Additional examples of unexpected or loud noises are the sound of the starting of a motorcycle, the fireworks at Christmas, or a thunderclap.

37. For example, your child watches everyone when they move around the room and this distracts them from the activities or tasks he/she is doing.

Certificate of Translator

I, Rafaela Mena, of legal age, resident of San Juan, Puerto Rico, registered pharmacist in Puerto Rico with license number 2313, and professional translator accredited member in good standing of the American Translators Association, HEREBY CERTIFY that, to the best of my knowledge and abilities, the foregoing document, **Clarifying Guide Version 3**, is a true and faithful rendering into English of the original Spanish text which I have seen, as described herein.

In San Juan, Puerto Rico, today, June 16, 2010



H-22 Maracaibo Park Gardens
San Juan, Puerto Rico 00926
(787) 616-0715, fay.mena@gmail.com

Rafaela Mena, RPh, MA

Guía para aclarar dudas al contestar el Breve Perfil Sensorial en español

Esta guía incluye ejemplos relacionados con algunos ítems que pueden ayudar a clarificar dudas que pueda tener mientras contesta el Breve Perfil Sensorial. Los ítems incluidos en la guía han sido seleccionados a base de recomendaciones ofrecidas por otros padres/cuidadores con quienes se discutió el cuestionario.

Mientras contesta el cuestionario, trate de pensar en diferentes situaciones (más de una si es posible) en que su niño(a) presenta la conducta descrita. Luego, conteste cada pregunta a base de la frecuencia con que observa esa conducta en su niño(a).

Sensibilidad táctil (Ítems 5, 6, 7)

5. Por ejemplo, no le gusta usar la pluma de arriba o ducha de la bañera, no le gusta que le salpique agua de la piscina, sentir las gotas de lluvia o que le salpique agua de un charco.

6. No le gusta sentir que otras personas están muy cerca de él/ella, como por ejemplo, cuando tiene que esperar en una fila o sentarse en círculo al lado de otros niños.

7. Por ejemplo, se limpia el área en que otra persona le haya dado un beso o en que otros niños le hayan tocado mientras jugaban.

Sensibilidad gustativa / olfatoria (Ítems 9, 10)

9. Piense en sabores. Por ejemplo, piense si su niño(a) evita comer cosas dulces o saladas.

10. Piense en texturas y temperaturas. Por ejemplo, piense si su niño(a) prefiere alimentos que estén bien calientes o bien fríos; o si sólo come alimentos de ciertas texturas (ej. Sólo texturas blandas- similares a la comida de bebé- "baby food"- puré de manzana, cremitas tipo avena, papa majada; o sólo texturas grumosas/ granosas como el arroz o los vegetales hervidos).

Sensibilidad al movimiento (Ítem 12)

12. Por ejemplo, cuando se mece, cuando un adulto lo carga, o cuando sube/escala algún juego en el parque (ej. Columpios, chorreras, sube y baja, etc.).

Poco sensible/ Busca sensación (Ítems 15, 16, 17, 18, 21)

15. Por ejemplo, le gusta tararear, cantar o hacer otros ruidos, ya sea mientras hace una tarea como por ejemplo, dibujar, o mientras juega con sus juguetes.

16. Por ejemplo, su niño(a) busca oportunidades para estar en movimiento, ya sea que se mueve mucho mientras está sentado en una silla, brinca sobre el sofá o sobre la cama o corre por el pasillo. Estas conductas hacen difícil la realización de tareas rutinarias como comer su almuerzo o cena, terminar de vestirse a tiempo o hacer las tareas escolares (por sí mismo o con la ayuda de otros).

17. Por ejemplo, le gustan tanto las actividades de movimiento (ej. brincar, correr, mecerse) que se vuelve hiperactivo, demasiado alerta o se le hace difícil dejar de hacer la actividad.

18. Piense si su niño(a) hace cualquiera de las siguientes: toca a personas (incluso, personas desconocidas o que no son familiares) o toca objetos. Por ejemplo, su niño(a) tiende abrazar o pegarse a las personas, o coge objetos en sus manos simplemente por cogerlos y sentir que tiene algo que tocar.

Filtro auditivo (Ítems 22, 24)

22. Por ejemplo, mientras está haciendo una tarea en una habitación, su niño(a) se distrae fácilmente con el ruido del televisor que está en otro cuarto, o por la conversación de otras personas en la habitación.

24. Ruido ambiental se refiere a aquellos ruidos que forman parte del lugar en que el niño(a) está trabajando o haciendo alguna actividad (por ejemplo, el ruido de un abanico, el ruido de un aire acondicionado, el ruido de los carros pasando por la calle).

Baja energía / débil (Ítems 28, 29, 32)

28. Por ejemplo, su niño(a) luce más débil en comparación con otros niños(as) de su edad.

29. Por ejemplo, mientras está caminando por la calle o parado en la fila de una tienda, su niño(a) se queja frecuentemente de que está cansado o le pide que lo coja al hombro.

32. Por ejemplo, su niño(a) se recuesta de la pared mientras está esperando en una fila, o se recuesta o deja caer sobre la mesa mientras hace una tarea sentado (ej. Colorear o escribir).

Sensibilidad visual/auditiva (Ítems 34, 37)

34. Ejemplos adicionales de ruidos inesperados son el sonido de una motora cuando la encienden, los fuegos artificiales en navidad o un trueno.

37. Por ejemplo, su niño(a) mira a cualquier persona que se esté moviendo cerca de la habitación y esto le distrae de las actividades o tareas que esté haciendo.

Certificate of Translator

I, Rafaela Mena, of legal age, resident of San Juan, Puerto Rico, registered pharmacist in Puerto Rico with license number 2313, and professional translator accredited member in good standing of the American Translators Association, HEREBY CERTIFY that, to the best of my knowledge and abilities, the foregoing document, **Clarifying Guide**, is a true and faithful rendering into Spanish of the original English text which I have seen, as described herein.

In San Juan, Puerto Rico, today, June 16, 2010



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Rafaela Mena, RPh, MA

APPENDIX C: CONSENT FORM FOR CAREGIVERS OF PRIVATE PRESCHOOLS
(ENGLISH AND SPANISH VERSIONS)

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: Sensory Modulation Disorder in Puerto Rican preschoolers: Associated risk factors

VCU IRB NO.: 4M13067

This consent form may contain words that you do not understand. Please ask the study staff to explain any words that you do not clearly understand. You are taking home a copy of this consent form to think about or discuss with family or friends before making your decision.

PURPOSE OF THE STUDY

The purposes of this research study are:

1. To examine the prevalence of Sensory Modulation Disorder (SMD) among a sample of Puerto Rican preschoolers
2. To examine if SMD is more common among preschoolers from high socioeconomic status (SES) or among preschoolers from low SES
3. To determine if there is a relationship between the presence of SMD and the following risk factors: low birth weight, pre-term delivery, lead exposure, alcohol consumption during pregnancy, and smoking during pregnancy

You are being asked to participate in this study because your child is a preschooler who attends a private preschool in the municipality of Guaynabo.

This study will be performed by Mrs. Rosa Román-Oyola, an occupational therapist practicing in Puerto Rico who is doctoral student of the Health Related Sciences Program of Virginia Commonwealth University; and by Dr. Stacey Reynolds, assistant professor of the Occupational Therapy Department of Virginia Commonwealth University.

DESCRIPTION OF THE STUDY AND YOUR INVOLVEMENT

If you decide to be in this research study, you will be asked to sign this consent form after you have had all your questions answered and understand what will happen to you.

In this study you will be asked to answer two questionnaires. One is the Spanish version of the Short Sensory Profile, which consists of 38 items about children's behaviors when exposed to sensations of daily life events (e.g., sensations during feeding, combing, bathing, among others daily events). The other questionnaire is a "Demographic and risk factors data sheet". That questionnaire consists of 10 items that will ask you to provide some socio-demographic information such as your educational level. It will also ask for information related to your child when he/she was born and about your behaviors during pregnancy, including smoking and drinking. Answering both questionnaires will take you approximately 30 minutes.

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The research staff does not want to inconvenience you by asking you to fill four questionnaires in case that you have siblings attending Head Start at this moment. Thus, if you have siblings attending Head Start, we have randomly decided to ask you to answer questionnaires only about your ☐ younger / ☐ older child.

RISKS AND DISCOMFORTS

Sometimes, people might feel uncomfortable while answering questions about themes like their income, their children's behavior, or about things they did during the prenatal period of their children. You will not have to provide information about any subject that discomforts you while answering the questionnaires. It is your right to retire from this study at any time you wish.

BENEFITS TO YOU AND OTHERS

If you wish, you can provide your postal address in the attached form and a summary of your child's results on the Short Sensory Profile will be mailed to you within three weeks after you return the questionnaires.

In addition, your participation in this study implies a contribution to the scientific knowledge base of Sensory Modulation Disorder. This might help in the design of better prevention and intervention programs for specific populations.

In addition, your participation in this study may or may not help us to better understand Sensory Modulation Disorder and to design better prevention and intervention programs for specific populations.

COSTS

There are no costs for participating in this study other than the time you will spend completing the questionnaires.

PAYMENT FOR PARTICIPATION

You will receive a \$10.00 gift card for participating in this study. It will be mailed to the postal address you provide in the attached form within three weeks after your return the questionnaires.

CONFIDENTIALITY

Potentially identifiable information about you will consist of questionnaires' written responses. Data is being collected only for research purposes. Neither your name, nor the name of your child, will appear on the questionnaires. Instead, a code number will be written on the questionnaires.

Data from the questionnaires will be stored in a locked archive at at Mrs. Román-Oyola's home for six months. They will be destroyed after the study ends.

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Access to all data will be limited to the researcher. The answers you give on the questionnaires will not be told to anyone; however information from the study and the consent form signed by you may be looked at or copied for research or legal purposes by Virginia Commonwealth University. Findings from this study may be presented at meetings or published in papers, but your name and personal information will not ever be used in these presentations or papers.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

You do not have to participate in this study. If you choose to participate, you may stop at any time without any penalty. You may also choose not to answer particular questions that are asked in the study. Whether you participate in the study or not, will have no effect on the services you and your child receives from the school

QUESTIONS

In the future, you may have questions about your participation in this study. If you have any questions, complaints, or concerns about the research, contact:

- Dr. Stacey Reynolds, professor of the Occupational Therapy Department of Virginia Commonwealth University – 352-273-6126, reynoldsse3@vcu.edu
- Mrs. Rosa Román-Oyola, graduate student - 787-365-9859, romanoyolar@vcu.edu
Postal address: PO Box 195640 San Juan, PR 00919-5640

If you have any questions about your rights as a participant in this study, you may contact:

Office for Research
Virginia Commonwealth University
800 East Leigh Street, Suite 113
P.O. Box 980568
Richmond, VA 23298
Telephone: 804-827-2157

You may also contact this number for general questions, concerns or complaints about the research. Please call this number if you cannot reach the research team or wish to talk to someone else. Additional information about participation in research studies can be found at <http://www.research.vcu.edu/irb/volunteers.htm>.

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CONSENT

I have been given the chance to read this consent form. I understand the information about this study. Questions that I wanted to ask about the study have been answered. My signature says that I am willing to participate in this study.

I will receive a copy of the consent form once I have agreed to participate.

Name of Child

Printed name of participant who completed the questionnaires

Signature of participant who completed the questionnaires

Date

Signature of Person Conducting Informed Consent
Discussion / Witness

Date


Principal Investigator Signature (if different from above)

Date

Certificate of Translator

I, Rafaela Mena, of legal age, resident of San Juan, Puerto Rico, registered pharmacist in Puerto Rico with license number 2313, and professional translator accredited member in good standing of the American Translators Association, HEREBY CERTIFY that, to the best of my knowledge and abilities, the foregoing document, **Consent form**, is a true and faithful rendering into English of the original Spanish text which I have seen as described herein.

In San Juan, Puerto Rico, today, **August 10, 2010**



Rafaela Mena, RPh, MA

H-22 Maracaibo Park Gardens
San Juan Puerto Rico 00926
(787) 616-0715, Fay.Mena@gmail.com

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FORMULARIO DE CONSENTIMIENTO E INFORMACIÓN PARA LOS PARTICIPANTES

TÍTULO: Desorden de Modulación Sensorial en niños puertorriqueños de edad preescolar: factores de riesgo asociados

VCU IRB NO.: HM13067

Este formulario de consentimiento puede contener palabras que usted no entienda. Por favor, pregunte al investigador o a cualquier personal del estudio que le explique cualquier palabra o información que usted no entienda claramente. Usted puede llevarse a su casa una copia de este formulario de consentimiento para pensar sobre su participación en este estudio o para discutirlo con la familia o amigos antes de tomar su decisión.

PROPÓSITO DEL ESTUDIO

Los propósitos de este estudio de investigación son:

1. Examinar la prevalencia del Desorden de Modulación Sensorial (DMS) en una muestra de niños preescolares puertorriqueños
2. Examinar si el DMS es más común entre niños preescolares de alto estatus socioeconómico (ESE) o entre preescolares de bajo ESE
3. Determinar si hay una relación entre la presencia del DMS y los siguientes factores de riesgo: bajo peso al nacer, nacimientos prematuros, exposición al plomo, consumo de alcohol durante el embarazo y fumar durante el embarazo.

Se le ha pedido participar en este estudio porque su niño(a) está en edad preescolar y asiste a un preescolar privado en el municipio de Guaynabo.

Este estudio será llevado a cabo por la Sra. Rosa Román-Oyola, terapeuta ocupacional ejerciendo en Puerto Rico y estudiante doctoral del programa de Ciencias Relacionadas con la Salud de Virginia Commonwealth University; y por la Dra. Stacey Reynolds, profesora del Departamento de Terapia Ocupacional de Virginia Commonwealth University.

DESCRIPCIÓN DEL ESTUDIO Y LO QUE CONLLEVA

Si usted decide participar en este estudio, se le solicitará firmar este formulario de consentimiento luego de que todas sus preguntas hayan sido contestadas y haya entendido lo que conlleva su participación.

En este estudio se le solicitará contestar dos cuestionarios. Uno es la versión en español del Breve Perfil Sensorial, el cual consiste de 38 preguntas acerca de la conducta del niño(a) cuando se expone a sensaciones de la vida diaria (ej. Sensaciones mientras come, se peina, se baña, entre otros eventos de la vida diaria). El otro cuestionario es una "Hoja de datos socio-demográficos y factores de riesgo". Ese cuestionario consiste en 10 preguntas que solicitan información socio-demográfica como por ejemplo, su nivel educativo. También contiene preguntas relacionadas

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Versión 2, 3 de agosto de 2010, Página 1 de 5

con su niño(a) cuando nació y acerca de sus conductas durante el embarazo, incluido si fumó o consumió alcohol. Contestar ambos cuestionarios le tomará aproximadamente 30 minutos.

El personal del estudio no desea causarle inconvenientes al pedirle llenar cuatro cuestionarios en caso de que usted tenga más de un niño(a) que asiste a Head Start. Por tanto, si usted tiene más de un niño(a) que asiste a Head Start, hemos decidido, al azar, pedirle que conteste los cuestionarios sólo acerca de su niño(a) ☐ mayor / ☐ menor.

RIESGOS E INCOMODIDADES

En ocasiones, las personas pueden sentirse incómodas al tener que contestar preguntas acerca de temas como su ingreso, la conducta de sus niños(as), o acerca de cosas que hicieron durante el período prenatal de sus niños(as). Usted no está obligado a proveer información acerca de cualquier tema que pudiera incomodarlo mientras contesta los cuestionarios. Usted está en su derecho de retirarse de este estudio en cualquier momento que lo desee.

BENEFICIOS

Si lo desea, puede proveer su dirección postal en el formulario adjunto y se le enviará un resumen con los resultados de su niño(a) en el Breve Perfil Sensorial dentro de un período de tres semanas luego de que usted haya devuelto los cuestionarios.

Además, su participación en este estudio podría o no ayudarnos a entender mejor la condición de Desorden de Modulación Sensorial y a diseñar mejores programas de prevención e intervención para poblaciones específicas.

COSTOS

Su participación en este estudio no conlleva ningún costo, excepto por el tiempo que invertirá llenando los cuestionarios.

PAGO POR PARTICIPACIÓN

Usted recibirá una tarjeta de regalo de \$10 por participar en este estudio. Se le enviará la tarjeta a la dirección postal que usted provea en el formulario adjunto dentro de tres semanas luego de que usted haya devuelto los cuestionarios.

CONFIDENCIALIDAD

La información que se recopile en este estudio que pueda identificarle consiste en sus respuestas escritas en los cuestionarios. Los datos serán utilizados sólo para propósitos de la investigación. Ni su nombre, ni el de su niño(a) aparecerán en los cuestionarios. Para identificarle se utilizará un código numérico que aparecerá en los cuestionarios que contestará.

Los datos de los cuestionarios se guardaran en un archivo bajo llave en casa de la Sra. Román-Oyola por seis meses. Serán destruidos luego de que el estudio haya terminado.

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Sólo las investigadoras tendrán acceso a la información recopilada. La información que usted provea en los cuestionarios no será compartida con nadie. Sin embargo, información acerca de este estudio, así como el formulario de consentimiento firmado por usted podría ser fotocopiada o solicitada para propósitos investigativos o legales por "Virginia Commonwealth University (VCU)". Los resultados de este estudio podría ser presentados en reuniones o publicaciones, pero su nombre e información personal nunca aparecerán en dichas presentaciones o publicaciones.

PARTICIPACIÓN VOLUNTARIA Y RETIRO

Usted no tiene que participar en este estudio. Si decide participar, puede retirarse del mismo en cualquier momento sin ninguna penalidad. Además, usted puede decidir no contestar algunas preguntas en particular que se hagan durante este estudio. Su decisión de participar o no en este estudio no afectará en ninguna manera los servicios que usted y su niño reciben en el preescolar.

PREGUNTAS

En el futuro, usted podría tener preguntas acerca de su participación en este estudio. Si usted tuviera alguna pregunta, queja, o preocupación acerca de este estudio, contacte a:

- Dra. Stacey Reynolds, profesora del Departamento de Terapia Ocupacional de "Virginia Commonwealth University" – 352-273-6126, reynoldsse3@vcu.edu
 - Sra. Rosa Román-Oyola, estudiante graduada - 787-365-9859, romanoyolar@vcu.edu
- Dirección postal: PO Box 195640 San Juan, PR 00919-5640

Si usted tiene alguna pregunta acerca de sus derechos como participante de este estudio, puede también comunicarse con:

Office of Research
Virginia Commonwealth University
800 East Leigh Street, Suite 113
P.O. Box 980568
Richmond, VA 23298
Teléfono: 804-827-2157

Puede, además comunicarse a este número para preguntas generales, preocupaciones, o quejas acerca de este estudio. Por favor, llame a este número si no logra comunicarse con el equipo de investigación o si desea hablar con alguna otra persona. Usted puede encontrar información adicional acerca de la participación en estudios de investigación accediendo:
<http://www.research.vcu.edu/irb/volunteers.htm>.

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CONSENTIMIENTO

He tenido la oportunidad de leer este formulario de consentimiento. Entiendo la información acerca de este estudio. Las preguntas que quería hacer han sido contestadas. Mi firma indica que estoy dispuesto(a) a participar en este estudio.

Recibiré una copia del formulario de consentimiento una vez haya aceptado participar.

Nombre del niño(a) _____

Nombre de la madre en letra de molde _____

Firma de la madre _____

Fecha _____

Nombre de la persona que discutió el consentimiento/testigo en letra de molde _____

Firma de la persona que discutió el consentimiento/testigo
en letra de molde _____

Fecha _____

Firma del investigador principal (si es diferente
a la que firmó arriba) _____

Fecha _____

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Certificate of Translator

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APPENDIX D: CONSENT FORM FOR CAREGIVERS OF HEAD START
PRESCHOOLS (ENGLISH AND SPANISH VERSIONS)

RESEARCH SUBJECT INFORMATION AND CONSENT FORM FOR PARTICIPANTS

TITLE: Sensory Modulation Disorder in Puerto Rican preschoolers: Associated risk factors

VCU IRB NO.: HM13067

This consent form may contain words that you do not understand. Please ask the study staff to explain any words that you do not clearly understand. You are taking home a copy of this consent form to think about or discuss with family or friends before making your decision.

PURPOSE OF THE STUDY

The purposes of this research study are:

1. To examine the prevalence of Sensory Modulation Disorder (SMD) among a sample of Puerto Rican preschoolers
2. To examine if SMD is more common among preschoolers from high socioeconomic status (SES) or among preschoolers from low SES
3. To determine if there is a relationship between the presence of SMD and the following risk factors: low birth weight, pre-term delivery, lead exposure, alcohol consumption during pregnancy, and smoking during pregnancy

You are being asked to participate in this study because your child is a preschooler who attends a Head Start in the municipality of Vieques, or a Head Start Program of the Toa Baja or Carolina Districts.

This study will be performed by Mrs. Rosa Román-Oyola, an occupational therapist practicing in Puerto Rico who is doctoral student of the Health Related Sciences Program of Virginia Commonwealth University; and by Dr. Stacey Reynolds, assistant professor of the Occupational Therapy Department of Virginia Commonwealth University.

DESCRIPTION OF THE STUDY AND YOUR INVOLVEMENT

If you decide to be in this research study, you will be asked to sign this consent form after you have had all your questions answered and understand what will happen to you.

In this study you will be asked to answer two questionnaires. One is the Spanish version of the Short Sensory Profile, which consists of 38 items about children's behaviors when exposed to sensations of daily life events (e.g., sensations during feeding, combing, bathing, among others daily events). The other questionnaire is a "Demographic and risk factors data sheet". That questionnaire consists of 10 items that will ask you to provide some socio-demographic information such as your educational level. It will also ask for information related to your child when he/she was born and about your behaviors during pregnancy, including smoking and drinking. Answering both questionnaires will take you approximately 30 minutes.

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You will also be asked to provide permission to the study staff to access your child's school record with the solely purpose of getting his results in the blood lead test you provide to the Head Start during the admission process.

The research staff does not want to inconvenience you by asking you to fill four questionnaires in case that you have siblings attending Head Start at this moment. Thus, if you have siblings attending Head Start, we have randomly decided to ask you to answer questionnaires only about your ☐ younger / ☐ older child.

RISKS AND DISCOMFORTS

Sometimes, people might feel uncomfortable while answering questions about themes like their income, their children's behavior, or about things they did during the prenatal period of their children. You will not have to provide information about any subject that discomforts you while answering the questionnaires. Similarly, your child's results on the blood lead test will be accessed only if you give your permission. It is your right to retire from this study at any time you wish.

BENEFITS TO YOU AND OTHERS

If you wish, you can provide your postal address in the attached form and a summary of your child's results on the Short Sensory Profile will be mailed to you within three weeks after you return the questionnaires. This will be done even if you do not give permission to access the results of your child's blood lead test.

In addition, your participation in this study may or may not help us to better understand Sensory Modulation Disorder and to design better prevention and intervention programs for specific populations.

COSTS

There are no costs for participating in this study other than the time you will spend completing the questionnaires.

PAYMENT FOR PARTICIPATION

You will receive a \$10.00 gift card for participating in this study. It will be mailed to the postal address you provide in the attached form within three weeks after your return the questionnaires.

CONFIDENTIALITY

Potentially identifiable information about you will consist of questionnaires' written responses and blood lead test results of your child. Data is being collected only for research purposes. Neither your name, nor the name of your child, will appear on the questionnaires. Instead, a code number will be written on the questionnaires. The first and second last names of your child will be included in a list that will be used to ask the school personnel for the children records. First

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names' initials will also be included on that list only in cases where there are siblings in the same preschool or more than one child with the same last names. However, the table in which the blood lead test's result of your child will be written will not include identifiable information of him/her or you. It will only have the results of the tests accompanied by the code number used in the questionnaires.

Data from the questionnaires and from lead tests will be stored in a locked archive at Mrs. Román-Oyola's home for six months. They will be destroyed after the study ends.

Access to all data will be limited to the researcher. The answers you give on the questionnaires or the results of your child's lead test will not be told to anyone; however information from the study and the consent form signed by you may be looked at or copied for research or legal purposes by Virginia Commonwealth University. Findings from this study may be presented at meetings or published in papers, but your name and personal information will not ever be used in these presentations or papers.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

You do not have to participate in this study. If you choose to participate, you may stop at any time without any penalty. You may also choose not to answer particular questions that are asked in the study, or you may decide that you do not want to give permission to access your child record. Whether you participate in the study or not, will have no effect on the services you and your child receives from the school.

QUESTIONS

In the future, you may have questions about your participation in this study. If you have any questions, complaints, or concerns about the research, contact:

- Dr. Stacey Reynolds, professor of the Occupational Therapy Department of Virginia Commonwealth University – 352-273-6126, reynoldsse3@vcu.edu
 - Mrs. Rosa Román-Oyola, graduate student - 787-365-9859, romanoyolar@vcu.edu
- Postal address: PO Box 195640 San Juan, PR 00919-5640

If you have any questions about your rights as a participant in this study, you may contact:

Office for Research
Virginia Commonwealth University
800 East Leigh Street, Suite 113
P.O. Box 980568
Richmond, VA 23298
Telephone: 804-827-2157

You may also contact this number for general questions, concerns or complaints about the research. Please call this number if you cannot reach the research team or wish to talk to

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someone else. Additional information about participation in research studies can be found at <http://www.research.vcu.edu/irb/volunteers.htm>.

CONSENT

I have been given the chance to read this consent form. I understand the information about this study. Questions that I wanted to ask about the study have been answered. My signature says that I am willing to participate in this study by (please mark one of the following):

- ☐ *Completing the attached questionnaires and giving permission to the study staff to access my child school record to obtain the results of his/her blood lead test*
☐ *Completing the attached questionnaires only*

I will receive a copy of the consent form once I have agreed to participate.

 Name of Child

 Printed name of the mother

 Signature of the mother

 Date

 Signature of Person Conducting Informed Consent
 Discussion / Witness

 Date

 Principal Investigator Signature (if different from above)

 Date

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Certificate of Translator

I, Rafaela Mena, of legal age, resident of San Juan, Puerto Rico, registered pharmacist in Puerto Rico with license number 2313, and professional translator accredited member in good standing of the American Translators Association, HEREBY CERTIFY that, to the best of my knowledge and abilities, the foregoing document, **Consent form**, is a true and faithful rendering into English of the original English text which I have seen as described herein.

In San Juan, Puerto Rico, today, **August 10, 2010**



Rafaela Mena, RPh, MA

H-22 Maracaibo Park Gardens
San Juan Puerto Rico 00926
(787) 616-0715, Fay.Mena@gmail.com

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FORMULARIO DE CONSENTIMIENTO E INFORMACIÓN PARA LOS PARTICIPANTES

TÍTULO: Desorden de Modulación Sensorial en niños puertorriqueños de edad preescolar: factores de riesgo asociados

VCU IRB NO.: 4413067

Este formulario de consentimiento puede contener palabras que usted no entienda. Por favor, pregunte al investigador o a cualquier personal del estudio que le explique cualquier palabra o información que usted no entienda claramente. Usted puede llevarse a su casa una copia de este formulario de consentimiento para pensar sobre su participación en este estudio o para discutirlo con la familia o amigos antes de tomar su decisión.

PROPÓSITO DEL ESTUDIO

Los propósitos de este estudio de investigación son:

1. Examinar la prevalencia del Desorden de Modulación Sensorial (DMS) en una muestra de niños preescolares puertorriqueños
2. Examinar si el DMS es más común entre niños preescolares de alto estatus socioeconómico (ESE) o entre preescolares de bajo ESE
3. Determinar si hay una relación entre la presencia del DMS y los siguientes factores de riesgo: bajo peso al nacer, nacimientos prematuros, exposición al plomo, consumo de alcohol durante el embarazo y fumar durante el embarazo.

Se le ha pedido participar en este estudio porque su niño(a) está en edad preescolar y asiste a un Head Start en el municipio de Vieques, o a un Programa de Head Start en los Distritos de Toa Baja o Carolina.

Este estudio será llevado a cabo por la Sra. Rosa Román-Oyola, terapeuta ocupacional ejerciendo en Puerto Rico y estudiante doctoral del programa de Ciencias Relacionadas con la Salud de Virginia Commonwealth University; y por la Dra. Stacey Reynolds, profesora del Departamento de Terapia Ocupacional de Virginia Commonwealth University.

DESCRIPCIÓN DEL ESTUDIO Y LO QUE CONLLEVA

Si usted decide participar en este estudio, se le solicitará firmar este formulario de consentimiento luego de que todas sus preguntas hayan sido contestadas y haya entendido lo que conlleva su participación.

En este estudio se le solicitará contestar dos cuestionarios. Uno es la versión en español del Breve Perfil Sensorial, el cual consiste de 38 preguntas acerca de la conducta del niño(a) cuando se expone a sensaciones de la vida diaria (ej. Sensaciones mientras come, se peina, se baña, entre otros eventos de la vida diaria). El otro cuestionario es una "Hoja de datos demográficos y factores de riesgo". Ese cuestionario consiste en 10 preguntas que solicitan información socio-

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demográfica como por ejemplo, su nivel educativo. También contiene preguntas relacionadas con su niño(a) cuando nació y acerca de sus conductas durante el embarazo, incluido si fumó o consumió alcohol. Contestar ambos cuestionarios le tomará aproximadamente 30 minutos.

Además, se le pedirá dar permiso al personal del estudio para acceder el expediente escolar de su niño(a) con el único propósito de obtener los resultados de la prueba de plomo en la sangre que se le realizó durante el proceso de admisión a Head Start.

El personal del estudio no desea causarle inconvenientes al pedirle llenar cuatro cuestionarios en caso de que usted tenga más de un niño(a) que asiste a Head Start. Por tanto, si usted tiene más de un niño(a) que asiste a Head Start, hemos decidido, al azar, pedirle que conteste los cuestionarios sólo acerca de su niño(a) ☐ mayor / ☐ menor.

RIESGOS E INCOMODIDADES

En ocasiones, las personas pueden sentirse incómodas al tener que contestar preguntas acerca de temas como su ingreso, la conducta de sus niños(as), o acerca de cosas que hicieron durante el período prenatal de sus niños(as). Usted no está obligado a proveer información acerca de cualquier tema que pudiera incomodarle mientras contesta los cuestionarios. Además, los resultados de su niño(a) en la prueba de plomo en la sangre serán accedidos solamente si usted da su permiso. Usted está en su derecho de retirarse de este estudio en cualquier momento que lo desee.

BENEFICIOS

Si lo desea, puede proveer su dirección postal en el formulario adjunto y se le enviará un resumen con los resultados de su niño(a) en el Breve Perfil Sensorial dentro de un período de tres semanas luego de que usted haya devuelto los cuestionarios. Esto se hará aún si usted decide no dar permiso para que el personal del estudio acceda los resultados de la prueba de plomo en la sangre de su niño(a).

Además, su participación en este estudio podría o no ayudarnos a entender mejor la condición de Desorden de Modulación Sensorial y a diseñar mejores programas de prevención e intervención para poblaciones específicas.

COSTOS

Su participación en este estudio no conlleva ningún costo, excepto por el tiempo que invertirá llenando los cuestionarios.

PAGO POR PARTICIPACIÓN

Usted recibirá una tarjeta de regalo de \$10 por participar en este estudio. Se le enviará la tarjeta a la dirección postal que usted provea en el formulario adjunto dentro de tres semanas luego de que usted haya devuelto los cuestionarios.

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CONFIDENCIALIDAD

La información que se recopile en este estudio que pueda identificarle consiste en sus respuestas escritas en los cuestionarios y los resultados de la prueba de plomo en la sangre de su niño(a). Los datos serán utilizados sólo para propósitos de la investigación. Ni su nombre, ni el de su niño(a) aparecerán en los cuestionarios. Para identificarle se utilizará un código numérico que aparecerá en los cuestionarios que contestará. Se utilizarán los dos apellidos de su niño(a) para preparar una lista que se entregará al personal de la escuela para que le permita acceder al personal de la investigación el expediente de su niño. También se incluirá la inicial del primer nombre del niño sólo en aquellos casos en que haya hermanos(as) en el mismo preescolar o en que más de un niño tenga los mismos apellidos. Sin embargo, la tabla en que se anotarán los resultados de las pruebas de plomo en la sangre no tendrá información que pueda identificarle a su niño o a usted. Sólo incluirá los resultados de la prueba junto al código numérico de los cuestionarios que usted contestó.

Los datos de los cuestionarios y de las pruebas de plomo se guardarán en un archivo bajo llave en casa de la Sra. Román-Oyola por seis meses. Serán destruidos luego de que el estudio haya terminado.

Sólo las investigadoras tendrán acceso a la información recopilada. La información que usted provea en los cuestionarios y los resultados de la prueba de plomo de su niño(a) no serán compartidos con nadie. Sin embargo, información acerca de este estudio, así como el formulario de consentimiento firmado por usted podría ser fotocopiada o solicitada para propósitos investigativos o legales por "Virginia Commonwealth University (VCU)". Los resultados de este estudio podría ser presentados en reuniones o publicaciones, pero su nombre e información personal nunca aparecerán en dichas presentaciones o publicaciones.

PARTICIPACIÓN VOLUNTARIA Y RETIRO

Usted no tiene que participar en este estudio. Si decide participar, puede retirarse del mismo en cualquier momento sin ninguna penalidad. Además, usted puede decidir no contestar algunas preguntas en particular que se hagan durante este estudio, o decidir que no desea dar permiso para acceder el expediente de su niño(a). Su decisión de participar o no en este estudio no afectará en ninguna manera los servicios que usted y su niño reciben en el preescolar.

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PREGUNTAS

En el futuro, usted podría tener preguntas acerca de su participación en este estudio. Si usted tuviera alguna pregunta, queja, o preocupación acerca de este estudio, contacte a:

- Dra. Stacey Reynolds, profesora del Departamento de Terapia Ocupacional de "Virginia Commonwealth University" – (352) 273-6126, reynoldsse3@vcu.edu
- Sra. Rosa Román-Oyola, estudiante graduada - 787-365-9859, romanoyolar@vcu.edu
Dirección Postal: PO Box 195640 San Juan, PR 00919-5640

Si usted tiene alguna pregunta acerca de sus derechos como participante de este estudio, puede también comunicarse con:

Office of Research
Virginia Commonwealth University
800 East Leigh Street, Suite 113
P.O. Box 980568
Richmond, VA 23298
Teléfono: 804-827-2157

Puede, además comunicarse a este número para preguntas generales, preocupaciones, o quejas acerca de este estudio. Por favor, llame a este número si no logra comunicarse con el equipo de investigación o si desea hablar con alguna otra persona. Usted puede encontrar información adicional acerca de la participación en estudios de investigación accediendo:
<http://www.research.vcu.edu/irb/volunteers.htm>.

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CONSENTIMIENTO

He tenido la oportunidad de leer este formulario de consentimiento. Entiendo la información acerca de este estudio. Las preguntas que quería hacer han sido contestadas. Mi firma indica que estoy dispuesto(a) a participar en este estudio (por favor, marque una de las siguientes):

☐ *Contestando los cuestionarios adjuntos y dando permiso al personal del estudio para acceder el expediente escolar de mi niño(a) para obtener los resultados de su prueba de plomo en la sangre.*

☐ *Contestando los cuestionarios adjuntos solamente.*

Recibiré una copia del formulario de consentimiento una vez haya aceptado participar.

Nombre del niño(a)

Nombre de la madre en letra de molde

Firma de la madre

Fecha

Nombre de la persona que discutió el consentimiento/testigo en letra de molde

Firma de la persona que discutió el consentimiento/testigo
en letra de molde

Fecha

Firma del investigador principal (si es diferente
a la que firmó arriba)

Fecha

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Certificate of Translator

I, Rafaela Mena, of legal age, resident of San Juan, Puerto Rico, registered pharmacist in Puerto Rico with license number 2313, and professional translator accredited member in good standing of the American Translators Association, HEREBY CERTIFY that, to the best of my knowledge and abilities, the foregoing document, **Consent Form**, is a true and faithful rendering into Spanish of the original English text which I have seen as described herein.

In San Juan, Puerto Rico, today, **August 10, 2010**



Rafaela Mena, RPh, MA

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San Juan Puerto Rico 00926
(787) 616-0715, Fay.Mena@gmail.com

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APPENDIX E: POSTAL ADDRESS FORM (ENGLISH AND SPANISH VERSIONS)

Sensory modulation in Puerto Rican preschoolers: Associated risk factors

Postal address form

Please complete this form only if you are interested in receiving a summary of your child's results in the Short Sensory Profile and a \$10 gift card as compensation for your participation in this study. You will receive these within three weeks after returning the two questionnaires (the Short Sensory Profile and the Demographic and risk factors data sheet).

Name: _____

Postal address: _____

Thanks for your participation in this study.

Certificate of Translator

I, Rafaela Mena, of legal age, resident of San Juan, Puerto Rico, registered pharmacist in Puerto Rico with license number 2313, and professional translator accredited member in good standing of the American Translators Association, HEREBY CERTIFY that, to the best of my knowledge and abilities, the foregoing document, **Mailing Address Form**, is a true and faithful rendering into English of the original Spanish text which I have seen, as described herein.

In San Juan, Puerto Rico, today, June 16, 2010



H-22 Maracaibo Park Gardens
San Juan Puerto Rico 00926
(787) 616-0715, fay.mena@gmail.com

Rafaela Mena, RPh, MA

Desorden de Modulación Sensorial en niños puertorriqueños de edad preescolar: factores de riesgo asociados

Formulario para proveer dirección postal

Por favor, complete este formulario sólo si está interesado en recibir un resumen con los resultados de su niño(a) en el Breve Perfil Sensorial y una tarjeta de regalo de \$10 como compensación por su participación en este estudio. Recibirá el resumen y la tarjeta de regalo dentro de un período de tres semanas después de haber devuelto los dos cuestionarios (el Breve Perfil Sensorial y la Hoja de datos demográficos y factores de riesgo).

Nombre: _____

Dirección postal: _____

Gracias por su participación en este estudio.

Certificate of Translator

I, Rafaela Mena, of legal age, resident of San Juan, Puerto Rico, registered pharmacist in Puerto Rico with license number 2313, and professional translator accredited member in good standing of the American Translators Association, HEREBY CERTIFY that, to the best of my knowledge and abilities, the foregoing document, **Mailing Address Form**, is a true and faithful rendering into Spanish of the original English text which I have seen, as described herein.

In San Juan, Puerto Rico, today, **June 16, 2010**



Rafaela Mena, RPh, MA

H-22 Maracaibo Park Gardens

San Juan Puerto Rico 00926

(787) 616-0715, fay.mena@gmail.com

VITA

Rosa L. Román-Oyola was born on August 23, 1980 in Bayamón, Puerto Rico (PR), where she grew up. She completed a bachelor's degree in Occupational Therapy Sciences at the University of PR, Medical Sciences Campus on 2003; and a master degree in Educational Research and Evaluation at the University of PR, Río Piedras Campus on 2007. She has been working as a clinical OT for eight years intervening with children with Sensory Modulation Disorder, ADHD, Autism Spectrum Disorders and Learning disabilities. In 2007, she completed her certification in Sensory Integration. Her research experience includes works related to the themes of sensory processing, validity of measurement tools when used with different populations, educational program evaluations, and population disparities in educational settings. Currently, in addition to work as a clinical OT, she works as part-time faculty in the OT program at the University of PR, Medical Sciences Campus.